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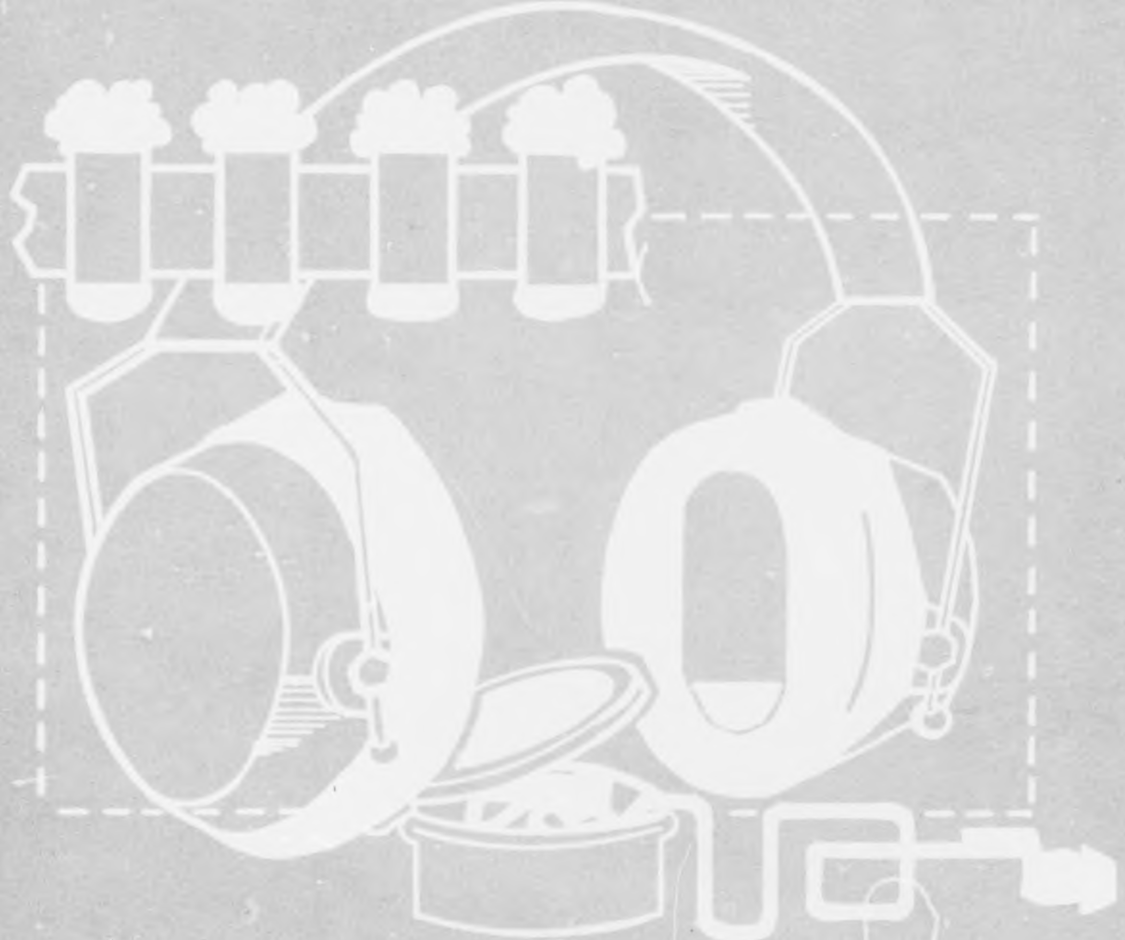

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This document contains information used by EPA in developing the Noise Labeling Requirements for Hearing Protectors including: a description of hearing protector devices, factors affecting selection, and a discussion of the various methods for measuring protector effectiveness; the procedure used to calculate single-number effectiveness ratings; an overview of the industry; the Agency's response to comments, and resolution of issues raised during the public comment period; and the participation of the public throughout the development of the regulation.

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PRODUCT NOISE LABELING REQUIREMENTS

REGULATORY ANALYSIS

SUPPORTING THE

LABELING OF HEARING PROTECTORS

August, 1979

U.S. Environmental Protection Agency
Office of Noise Abatement and Control
Washington, D.C. 20460

FOREWORD

This Regulatory Analysis has been prepared by the Environmental Protection Agency in support of Noise Labeling Requirements for Hearing Protectors. The regulation is promulgated under the authority of sections 8, 10, 11 and 13 of the Noise Control Act of 1972.

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INTRODUCTION

In the Noise Control Act of 1972 (86 Stat. 1234) Congress declares that "it is the policy of the United States to promote an environment for all Americans free from noise that jeopardizes their health or welfare." Congress further declares that one purpose of this Act is "to provide information to the public respecting the noise emission and noise reduction characteristics of products (distributed in commerce)."

Section 8 of the Act (Labeling) requires that the Administrator of the Environmental Protection Agency shall by regulation designate any product or class of product "which emits noise capable of adversely affecting the public health or welfare; or which is sold wholly or in part on the basis of its effectiveness in reducing noise." Further, the Administrator must require by regulation that "notice be given to the prospective user (of a product) of the level of the noise the product emits, or of its effectiveness in reducing noise, as the case may be." The regulation must specify: "...whether such notice should be affixed to the product or to the outside of its container, or to both, at the time of its sale to the ultimate purchaser or whether such notice shall be given to the prospective user in some other manner,"; "the form of the notice"; and "the method and units of measurement to be used (in the notice)."

The Agency has as its basic objectives in the development and the implementation of Federal noise labeling requirements for specific products under Section 8 of the Noise Control Act, the following elements:

1. To provide accurate and understandable information to prospective users of products regarding the acoustic properties of designated

products so that meaningful comparisons with respect to noise emission or noise reduction can be made as part of a product purchase or use decision.

2. To provide accurate and understandable information to prospective users with minimal Federal involvement. Minimal Federal involvement is to be achieved by ensuring that the Federally-imposed labeling requirements are carefully analyzed and structured so as to reduce the administrative, economic and technical impacts of the Federal program as much as possible.

Therefore, under the authority of and as required by Section 8 of the Noise Control Act of 1972, on December 5, 1974, the Agency published an Advanced Notice of Proposal Rulemaking (ANPRM) (39 FR 42380) [1] which stated that, in the first rulemaking under Section 8, the Agency intended to designate hearing protective devices as products sold wholly or in part on the basis of their effectiveness in reducing noise, and to require them to be labeled according to their noise reducing capability.

RATIONALE

The Agency initiated this regulatory development action because of the recognized usefulness of hearing protectors in certain noise environments.

Every noise environment contains three basic characterisitics: a noise source, a path along which the noise travels, and a receiver of the noise.

Typically, control of noise which adversely affects people is limited to reducing noise at its source, controlling its paths of propagation, or limiting --at the ear--the noise entering the ear.

In many instances, these controls of noise at the source or along the propagation path are either lacking or are inadequate to reduce the level of the noise sufficiently to protect the hearing of someone exposed to the noise.

In these situations, the use of hearing protectors may be the only practical means of noise control on a short-term basis.

Hearing protectors are principally sold on the basis of their ability to attenuate the level of sound entering a person's ear. The amount of sound attenuation provided by the broad range of insert and muff type protectors, currently on the market varies widely. There are devices designed primarily to prevent water from entering a swimmer's ears that are frequently misused as hearing protectors. There are devices that can be purchased merely to reduce annoying sounds in a person's environment to levels that may permit sleep, study or relaxation. While these devices may afford a measure of sound reduction, their effectiveness in high noise environments may be marginal. Users of devices which give insufficient hearing protection for a particular noise environment can sustain permanent hearing loss because of exposure to levels of noise from which they believe they are protected.

For a prospective user of hearing protective devices to make an informed choice of a protector that will provide adequate protection in a particular noise environment, that person must be able to determine the level of hearing protection offered by a given hearing protector, and its effeciveness relative to other protectors. This information is not now available to an ultimate purchaser or a prospective user in a easily understood and readily visible manner.

While manufacturers have measured the effectiveness of their products, they in general do not convey this information to prospective users. Those few that do, do not relay effectiveness information in a uniform manner for similar categories of protectors; nor is comarative range information available upon which protector selections adequate for a users need can be made.

The Agency's intent in initiating the development of a regulation concerning the labeling of hearing protectors, was to provide information to prospective users on the noise reducing effectiveness of these products at the point of sale or at the point of distribution (e.g., industrial users). This information will provide the basis for selection of a protector best suited to the user's needs.

To fulfill the Agency's own objectives of providing accurate and understandable information, and that any labeling requirements be carefully analyzed and structured so as to reduce administrative, economic and technical impacts as much as possible, the Agency established a public comment period for 60 days, and solictied information relative to all aspects associated with the labeling of hearing protectors, specifically:

1. Information on the different types, makes and model of hearing protectors being sold, their packaging, manufacturing costs, and wholesale prices;
2. What information is now being provided to purchasers regarding the effectiveness of hearing protectors, and the manner and techniques used to to relay that information;
3. Discussions of recommended methods for classifying hearing protectors and other parameters which could be used as descriptors in a classification scheme;
4. The test procedures currently in use or under development to determine noise attenuation capabilities of hearing protectors, and the test procedures which could be used;
5. Information on the shelf life and use life of hearing protectors;
6. Hazards asssociated with the improper use of hearing protectors, or

devices or products inappropriately used as hearing protectors;

7. Information and suggestions in the form a label for hearing protectors should take, and what information should appear on the label in order to meaningfully convey the noise attenuation capability of the hearing protector to the prospective user; and

8. Information regarding the number of hearing protectors produced for distribution per year in the United States, the number of hearng protectors imported for distribution in commerce, the number of manufacturers or importers involved in the total market, and relative market shares.

We received a total of 9 written comments to the ANPRM docket from: the hearing protector industry and trade associations; laboratories involved in acoustic testing; and government agencies that use protectors or specify protector effectiveness, construction, composition or packaging requirements. These commenters recommended measurement standards, label placement and content, questioned the validity of single number rating schemes, and submitted examples of various protector characteristics and packaging.

Because of the limited data received from comments to the ANPRM, the Agency sent letters to selected manufacturers of hearing protectors in an effort to obtain information on manufacturing costs, manufacturing processes, marketing processes, extent of the market, numbers and types of protectors manufactured, and each manufacturer's share of the market to adequately assess the effects of a labeling requirement on the industry and the public.

LABELING APPROACH

The approach the Agency took in developing its Section 8 noise labeling requirements was to study product labeling in general and then labeling with respect to a product to noise-emitting or noise reducing capabilities. Hearing protectors were then studied specifically. The study of the aspects of product labeling in common use, and their applicability to Agency regulatory requirements, led the Agency to conclude that certain elements of labeling can be applied uniformly when regulating all product classes. These common elements are format and content of the label, label location, and basic regulatory enforcement procedures. These "general provisions" were published as a Notice of Proposed Rulemaking (NPRM) on June 22, 1977 in the Federal Register (42 FR 31722) [2].

By proposing the General Provisions for Product Noise Labeling, the Agency intended to provide guidance to the general public, and to all potentially affected parties, on the general nature and intent of the product noise labeling program, and set forth the general approach the Agency would follow when regulating specific products or classes of products. Product manufacturers and suppliers potentially affected by noise labeling requirements would then have substantial lead-time to either formulate voluntary labeling programs that would satisfy EPA's labeling requirements or to prepare for possible Federal noise labeling regulatory action. The general labeling requirements would apply to all noise-producing and noise-reducing products, and would eliminate the need to re-propose many of the same regulatory requirements in each product-specific labeling action. Each regulation specific to a product would clearly delineate any exceptions to the general provisions, modifications of the general provisions or additional provisions necessary to adequately regulate a product. Thus, a complete Section 8 labeling action by the Agency would consist of those general provisions that are applicable to a specific product and the product-specific regulation.

The NPRM proposed the Product Noise Labeling program as a new Part 211 of Title 40 of the Code of Federal Regulations (40 CFR) with the General Provisions to be Subpart A.

The Agency, at the same time, published the Notice of Proposed Rulemaking (NPRM) on the labeling requirements for hearing protectors (42 FR 31730) [3], which would be included in 40 CFR Part 211 as Subpart B.

The NPRM on the labeling of hearing protectors proposed to require: that all manufacturers of hearing protective devices label each device as to its effectiveness in reducing noise entering the ear; a uniform test methodology for determining the noise reducing effectiveness of hearing protectors; and a uniform scheme - the Noise Reduction Rating (NRR) - for rating the effectiveness of all hearing protectors. The NPRM also proposed to require that noise attenuating information, statements on fit, and a cautionary note supporting the label NRR be included in the protector packaging. It presented the detailed enforcement procedures that would be used by the Agency to assure manufacturers' compliance with the labeling requirements, and the conditions under which special claims or exceptions could be requested.

PUBLIC PARTICIPATION:

At the time of publication of the proposal, EPA solicited written public comment by means of direct mailings of information about the regulation to manufacturers, trade associations, other Federal Agencies, State and local governments, test laboratories, educational institutions, users of hearing protectors, and others.

The information provided was in the form of fact sheets, copies of the proposed regulation, and press releases generally dexcribing the proposal.

A public comment period on the NPRM extended from June 22, 1977 to September 22, 1977; public hearings were defered pending public response. During this period, the Agency received 52 written comments. It also received 3 oral and 7 written comments pertaining to hearing protectors which had been directed to the concurrently established public comment period for the proposed General Provisions (Subpart A) for Product Noise Labeling (40 CFR Part 211).

The Agency decided that a public meeting was in the best public interest in order to fully understand problems the hearing protector industry expressed in their written comments, and to better clarify certain elements of the proposed rule.

The public meeting was announced in the Federal Register on December 2, 1977 (42 FR 61289) and held on December 13, 1977, at the Office of Noise Abatement and Control in Arlington, Virginia. Attendees included manufacturers, the industry trade association, several members of the user industry, and Federal representatives. Oral comments were received from 10 speakers. A transcript of the proceedings of this meeting along with the listing of attendees has been made available at EPA's office of Public Information, 401 M Street, SW, Washington, DC 20460.

Comments from private citizens and industrial users for the most part supported the labeling of hearing protectors as to their noise reducing effectiveness. Comments from manufacturers and related groups were critical of certain elements of the program, but were not generally opposed to placing an effectiveness rating on their hearing protectors.

The Agency carefully reviewed and considered all information received from the manufacturing industry and related organizations, the user industries, government organizations, and the general public on the potential impact a Federal labeling requirement might engender on the cost of hearing protectors on manufacturers' production processes and on their packaging procedures. The Agency reassessed the designated test methodology, availability of test facilities, enforcement procedures, and labelng responsibilities and made various changes and clarifications in response to the public comments.

The Agency published the final rule, Noise Labeling Requirements for Hearing Protectors, in Volume 44 of the Federal Register, in August of 1979.

To provide adequate notice to the public on the provisions of the final rule, the Agency developed explanatory material in the form of letters of introduction, fact sheets, questions and answers, press releases, a "Backgrounder" and reprints of the Federal Register. These items were mailed to manufactures, distributers, retailers, consumer groups, unions, trade associations, educational institutions, import/export interests, State and local governments, newspapers and consumer oriented media, and any other interested parties the Agency was able to identify. An abbreviated list of parties contacted is included in Appendix C of this document.

OUTLINE AND SUMMARY OF THE REGULATORY ANALYSIS

This regulatory analysis presents the results of studies carried out by the United States Environmental Protection Agency during its development of a proposed regulation requiring the labeling of all hearing protectors with respect to their effectiveness in reducing the level of noise entering a user's ear.

This document also contains a detailed descussion of all comments the Agency received during the Public Comment Period and the basis for resolution of all issues raised.

This analysis is divided into two parts:

PART I. The Development of the Noise Labeling of Hearing Protectors.

Section 1. Includes a description of hearing protective devices, performance characteristics of these devices, and a review of testing methodologies for measuring attenuation characteristics of hearing protectors.

Section 2. Includes an overview of the hearing protector industry, and the estimated economic affects associated with the labeling of hearing proprotectors.

PART II. Docket Analysis

The docket is the record of the comments received from all interested parties concerning the proposed regulation on the labeling of hearing protectors. Respondents are identified in the analysis by a docket number assigned to their entry when received into the docket. The primary function of the Docket Analysis is to present the public's view and comments relative to this rulemaking action and the Agency's reponse to all comments and issues raised.

Section 1.	Addresses issues concerning the Agency's statutory authority, and other general issues concerning the labeling of hearing protectors.
Section 2.	Addresses issues that concern the information the label will contain.
Section 3.	Addresses exceptions to the labeling requirement.
Section 4.	Addresses placement and size of the label, and related concerns.
Section 5.	Addresses the effectiveness rating, test methodology, and laboratory facilities.
Section 6.	Addresses issues pertaining to enforcement procedures.
Section 7.	Addresses issues related to an economic analysis of noise labeling of hearing protectors.
Appendix A.	Presents the definition of issues from each docket entry, both written comments and oral testimony.
Appendix B.	Is an index of all docket submissions, written and oral, which allows one to identify the sources of comments not specifically mentioned in the text.
Appendix C.	Is an abbreviated list of the parties contacted through the Agency's public participation program.
Appendix D.	Is a list of the manufacturers and distributors of hearing protectors.

PART I

THE DEVELOPMENT OF THE NOISE LABELING OF HEARING PROTECTORS

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SECTION I

DESCRIPTION OF HEARING PROTECTIVE DEVICES AND THEIR PERFORMANCE CHARACTERISTICS

1.1 DESCRIPTION OF AVAILABLE DEVICES

A wide variety of devices that can fit in or over the ear, such as cigarette filters, dimes, pencil erasers, and cigar butts, have been used to keep noise from entering the ear. Cotton wadding inserted into the ear was used widely during World War I. In the 1940's, cotton was found to be ineffective and considerable attention was devoted to developing truly effective devices. The product of these early efforts was an earplug known as the V51R.

Industrial and commercial hearing protectors presently available may be classified as:

- ear insert devices;
- ear cap devices;
- ear muff devices; and
- combination devices.

EAR INSERT DEVICES

These devices are designed to fit into the ear canal. A variety of different types of insert devices have been developed. They may be conveniently discussed as a) pre-molded, b) malleable, and c) custom molded.

a) Pre-Molded Inserts

These devices are molded of soft, flexible rubber or plastic compounds into uniform shapes. They are often flanged and come in various sizes to accommodate the wide range of ear canal geometry. Some of these inserts are straight and symmetrical while others are shaped to conform more to curved

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ear canals. Most pre-molded devices are designed for substantial re-use and, therefore, are washable. Some pre-molded devices are intended to be discarded after limited use.

Pre-molded insert devices are relatively inexpensive. However, the prices per pair can vary considerably between those devices purchased in bulk quantities and those devices purchased as a single pair. Disposable insert devices may cost 10 cents when purchased in bulk quantities from a distributor, while a single pair of reusable devices may cost up to $7.00 if purchased from a retail store. Often the carrying case or the display packaging costs more than the device itself.

These devices, when properly cared for, are capable of providing hearing protection for extended periods of time. The the useful life of the protector is governed primarily by the materials used to make the device, which may shrink, crack, or, with time, lose the resiliency needed to assure proper, comfortable fit. Ear wax will cause some molded plugs to shrink and harden after a period of time, because the wax tends to extract from the plug the chemical constituents that keep it soft and pliable; this chemical reaction varies from person to person. The typical life of a reusable device can be as low as 5 to 6 weeks, but for most, it is about 6 months.

b) Malleable Inserts

These devices are, for the most part, intended to be disposable. Their use may range from 1 to 3 days before replacement is necessary. They are made from materials such as plastic foam, fine glass fibers, and wax-impregnated cotton. Malleable inserts are not pre-sized, but rather are personally molded to conform to each individual's ear canal. This is an advantage over pre-molded devices. However, the limited useful life of this type of device develops into a cost drawback if the user intends to use them on a continuing basis. The cost per pair ranges from 5 to 30 cents. Again, the price depends upon the quantity purchased, bulk purchase being the most economical.

Since the material must be kneaded before it is inserted in the ear, proper hygiene is required to prevent introducing dirt into the ear canal.

c) Custom Molded Inserts

Custom molded insert devices are permanently molded to the exact shape of an individual's ear. The fitting process can be somewhat complex, but it basically involves fitting the ear canal and outer ear with some pliable material to obtain the exact shape of the ear. This shape is then hardened to yield a permanent custom mold.

Typical materials used are plastic and silicone compounds. Hardeners that are added to these compounds to retain their custom fit, make the material remain pliable long enough for it to be inserted in the ear, make the mold, and then set permanently. Setting may require a few minutes to a full day.

With proper care custom molded devices may last from 2 to 3 years, and cost from $3.00 to $30.00 depending upon the materials used, quantities desired and the fabricator. These devices are generally more comfortable, but are not necessarily more effective than other devices; the materials occasionally contract while hardening, resulting in a slightly undersized protector.

EAR CAP DEVICES

These devices consist of two ear caps, designed to contact the outer edges of the ear canal. The caps are fastened to a headband that provides a compressive force on the caps to form a seal with the ear. Part of the cap fits slightly into the ear canal and the remainder spreads around the edge of the canal. They are generally molded from soft rubbery material and fit a large range of ear sizes. The caps last about 12 months and may be replaced for about $2.00 a pair. The initial cost of the device is from $3.00 to $5.00. Ear caps are intended to bridge the gap between inserts and ear muffs, having some of the advantages and disadvantages of each; for example, they are more expensive but more consistently effective than inserts, and are less expensive than ear muffs but do not fit as large a range of ear sizes. They do not seem to be in widespread use at the present time.

EAR MUFF DEVICES

These devices fit over the entire outer ear as opposed to within the ear canal. They consist of hard molded plastic cups held in place by a spring-loaded headband. The cups surround and cover the ear completely, forming a tight seal around the ear with a flexible vinyl sealing cushion filled with air, liquid or foam. Foam fillings are the most commonly found. In addition, the cups are lined with an acoustically absorbent material, usually foam sponge. The spring tension of the headband is critical in that it must allow minimum sound leakage between the muff and the ear, while accomodating varying head shapes. Many devices are designed to allow the headband to be worn over, under and/or behind the head to suit different personal preferences and use situations.

All parts of the ear muff that contact the skin can be washed with soap and water. The ear cups require periodic inspection for cracks or other damage. The ear seals are usually the first component to deteriorate, generally from perspiration. Most ear muffs have replaceable seals which can extend their useful life indefinitely.

The price of ear muffs varies in the range of $5.00 to $15.00.

COMBINATION DEVICES

There are a number of noise environments in which the need to protect hearing is only one of many important requirements. For example, the need for concise communication, the use of hard hats, and the use of welder shields would all require that, if hearing protective devices are to be worn, the devices must be made compatible with work requirements and safety precautions.

Any of the different types of hearing protective devices mentioned, ear inserts, caps or muffs, may be suitable for various use circumstances; however, special modifications and designs may be necessary to satisfy certain user needs. For example, ear muffs or inserts may be fitted with communication gear; helmets may be designed with built-in ear muffs or inserts; or hardhats may have muffs fastened directly to them with variously shaped headbands.

1.2 FACTORS AFFECTING SELECTION OF HEARING PROTECTIVE DEVICES

Two significant factors to be considered in selecting the proper hearing protective device for an in-use environment are the noise attenuating capability of the device and whether or not it will be worn. User acceptance to wearing the device is paramount to its effectiveness in reducing noise; obviously, the protectors cannot reduce noise if they are not worn.

In a work environment employers often must seek employee acceptance to wearing hearing protection, and then must further provide acceptable hearing protectors.

In a situation where an individual is purchasing a protector for his or her personal use, the need to wear hearing protection has already been accepted, and only selection of the appropriate protector remains.

For the individual or the employer to be able to choose the correct protector(s) for specific situations, the factors of overall noise attenuation capability and attenuation at specific frequencies are generally of primary importance. Factors such as use requirements/environment, fitability, comfort, care requirements, cost, biological compatibility, and durability must also be considered. However, some of these factors are subjective, so it is desirable to have a choice among hearing protective devices capable of adequate attenuation, but also capable of suiting different individual wearing preferences, or physiological constraints. These latter factors are not within the scope of the Agency's labeling authorities and therefore have not been considered in any detail in the studies presented here. They are, however, presented for general information.

ATTENUATION CAPABILITY

Since attenuation of noise is the purpose for which hearing protectors are used, special care must be taken to ensure that the measured attenuation is, in fact, indicative of that realized by the user. Virtually all tests of attenuation capability are conducted under strictly controlled laboratory conditions. Recently there has been concern that results obtained under these laboratory conditions are not truly indicative of the attenuation that is realized under in-use conditions. The National Institute for Occupational Safety and Health (NIOSH) has developed a field test procedure and conducted several field surveys to determine the difference between laboratory and in-use attenuation measurements. Early results [4] show a very poor correlation due, in part, to improper fit and user modifications.

Because of the importance of attenuation, it is treated separately in detail in Section 1.3.

USE REQUIREMENTS/ENVIRONMENT

The ultimate effectiveness of a hearing protector is not only dictated by its attenuation but also by the type of environmental conditions and use patterns in which hearing protectors will be needed. Such items as temperature and humidity, intermittent or continuous use, the need for compatibility with other personal safety devices, and workspace constraints play key roles. For example, wax-impregnated cotton inserts may be unsuitable for high temperature environments due to the softening or melting of the material; ear muffs may be best for intermittent use where the individual must go in and out of the noise environment frequently; ear muffs may not be suited to use with other equipment such as goggles or respirators; and inserts may be desirable where use is anticipated in very close quarters, such as might be required for machine repair and maintenance.

FITABILITY

Few devices, if any, will provide an optimum fit for everyone. However, proper fit is essential to realize the full attenuation potential of a device.

Much of the developmental efforts for hearing protectors have been directed to broadening the range of persons that a particular protector can fit properly. An example is the V51R ear insert which was originally manufactured in small, medium and large sizes, but later broadened to include extra-small and extra-large sizes to fit up to 95% of the population [4]. An extra-extra-large size would be necessary to obtain fit for 98% of the population. Another example is the triple-flanged insert, which was designed to fit everyone by providing three progressively larger concentric flanges. However, manufacture of three distinct sizes of this type of device was necessary to provide adequate fit for the large range of ear canal sizes. A final example is the expandable foam insert which is squeezed into a small cylinder, inserted into the ear canal, and allowed to expand to the individual shape of each canal. With this moldable device, reducing the original diameter of the foam cylinder provided an even greater range of ear canal fit.

In addition to initially providing a satisfactory fit, the hearing protective device must be able to maintain its fit during a variety of activities such as talking, chewing, and head movement. For inserted devices, this requires adequate depth of penetration and pressure on the ear canal. For devices employing muffs, flexible joints, proper ear cushions, and adequate headband tension are needed.

Fit is less of a problem for ear muff devices, but still requires special consideration. First, the device must necessarily cover the entire ear comfortable while allowing a minimum circumference for the cushion seal. Next, there must be a loose joint between headband and earcup to accommodate the range of skull curvatures encountered. Finally, the headband must be adjustable to allow for different sized heads and ear location. This is accomplished either by an adjustable headband, a movable ear cup, or both.

COMFORT

The major cause of discomfort is pressure exerted either on the ear canal by inserts or on the side of the head by muffs. However, pressure is required to create and maintain the seal that reduces noise leaks and allows the device to produce its intended attenuation. Thus, a major objective in the design of protective devices is to obtain a good fit in the canal or about the ear, while creating minimum discomfort for the wearer. This is accomplished by using soft, pliable materials and through various other design features. For inserts, the important factor in maintaining the proper fit of the protector in the ear is the sizing of the insert to the canal. For ear muffs, the critical factors required for a good fit are the ear cushion design and the pressure of the cushion against the head. Some inserts seal by assuming the shape of the ear canal while others use multiple soft flanges. Ear muffs use foam, air-filled, or liquid-filled cushions to comfortably seal the sound absorbing material with the contours of the head.

Another factor which can cause discomfort to the wearer is the weight of the device, thus introducing another design constraint. Since attenuation is related to the mass (or density) or materials used in constructing a device, a trade-off may be required between the attenuation capability of the device, and the comfort to the wearer.

BIOLOGICAL COMPATIBILITY

This factor is primarily a design consideration by the manufacturer. Before certain materials are used in the construction of hearing protective devices, tests are conducted to determine their compatibility with the chemistry of the human body. Some people can be particularly sensitive to certain materials used in protectors. In such cases irritation may result, making continued use of the protector difficult.

An inserted protector may tend to push ear wax inward toward the ear drum, causing a poor acoustic seal in addition to discomfort.

The tragus, which is the projection found in front of the external ear, in many individuals extends backwards over the ear canal opening, and may prevent the insertion of an insert device to its intended depth. The tragus may produce unequal pressure against the protective device, forcing the device backward and outward, thus displacing it enough to cause an acoustic leak which will reduce the potential noise reducing effectiveness of the device.

DURABILITY-USEFUL LIFE

The ability of a device to maintain its noise reducing effectiveness for a satisfactory period of time is an important consideration in terms of economical and effective hearing protection. How long will a device provide the rated attenuation? How long will it remain comfortable and maintain the proper fit? How long will it reamin hygienically acceptable? Devices age and deteriorate to varying degrees over varying spans of time. There is a lack of specific information regarding the real useful life of hearing protective devices. The useful life depends in large part upon the materials of which the device is made, environment in which it is used, and the care a person gives the device. Manufacturers can give general guidance, but it is necessary for the user to be sensitive to the physical changes that can occur in hearing protectors.

The National Institute for Occupational Safety and Health is field testing, for evaluation purposes, the practical hearing protection provided by various devices in actual use. Such testing permits evaluation of the actual attenuation provided by the devices (for comparison with stated attenuation values), and may, with time and repeated testing, develop some data on durability.

SUMMARY OF ADVANTAGES AND DISADVANTAGES

Some of the advantages and disadvantages of the currently available hearing protectors are summarized as follows:

Insert Type Devices

Advantages:

- small and easily carried;
- can be worn conveniently and effectively with other personally worn safety items;
- relatively comfortable to wear in hot environments;
- convenient for use where the head must be maneuvered in close quarters;
- the cost of pre-molded inserts is significantly less than that of all other protective devices; although inserts such as custom-molded devices may be comparable in price to other types of protectors such as muffs or ear caps.

Disadvantages:

- inserts require more time and skill to properly fit them than do muffs;

- the amount of attenuation provided at different frequencies by different plugs is more variable;
- proper hygiene is more difficult to maintain when devices must be removed and re-inserted;
- inserts can be worn only in healthy ear canals.

Muff Type Devices

Advantages:

- attenuation at different frequencies by different products is less variable;
- one size muff accommodates a large range of head sizes and shapes;
- muffs are more convenient when use is intermittent;
- muffs can be worn in spite of minor ear infections;
- muffs are not lost as easily as inserts.

Disadvantages:

- muffs can be uncomfortable in hot and/or humid environments;
- muffs are not easily carried or stored;
- muffs are not as compatible with other personally worn safety items;
- headband spring force may diminish with use, and reduce the protection provided;
- length of hair around the ear and use with eye glasses can diminish effectiveness.
- muffs may be awkward when used in close quarters;
- muffs are more expensive than most insert devices.

Ear Cap Devices

These devices seal the outer edge of the ear canal, and are the middle ground between inserts and muffs. As such, they have many of the disadvantages and advantages of each. They do not seem to be in widespread use at this time.

1.3 ATTENUATION/EFFECTIVENESS OF DEVICES

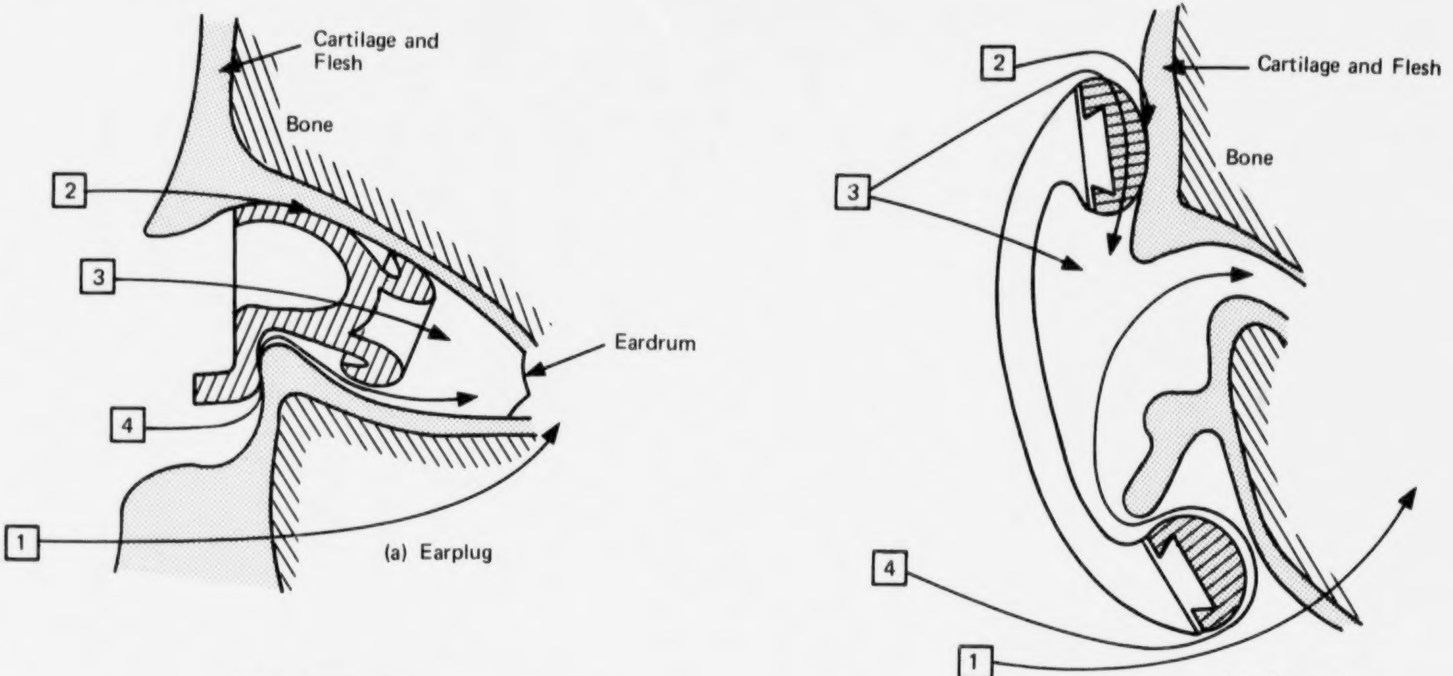
FACTORS AFFECTING ATTENUATION

Hearing protective devices are used, on a short-term basis, to reduce the level of noise entering the ear. Therefore the ability to attenuate noise is a major consideration in the selection of a device. Other factors pertinent to the selection of a protector for use in a specific environment may be balanced one against the other, but of primary concern is the amount of hearing protection required and the ability of a device to provide the necessary attenuation.

Noise may reach the inner ears of persons wearing protectors by four different paths: (1) transmission through bone and tissue, thus by-passing the protector; (2) vibration of the protector which, in turn, transmits a sound into the external ear canal rather than blocking it; (3) passing through air leaks in the protector; and (4) passing through noise leaks around the protector. These paths are illustrated in Figure 1.1 [5].

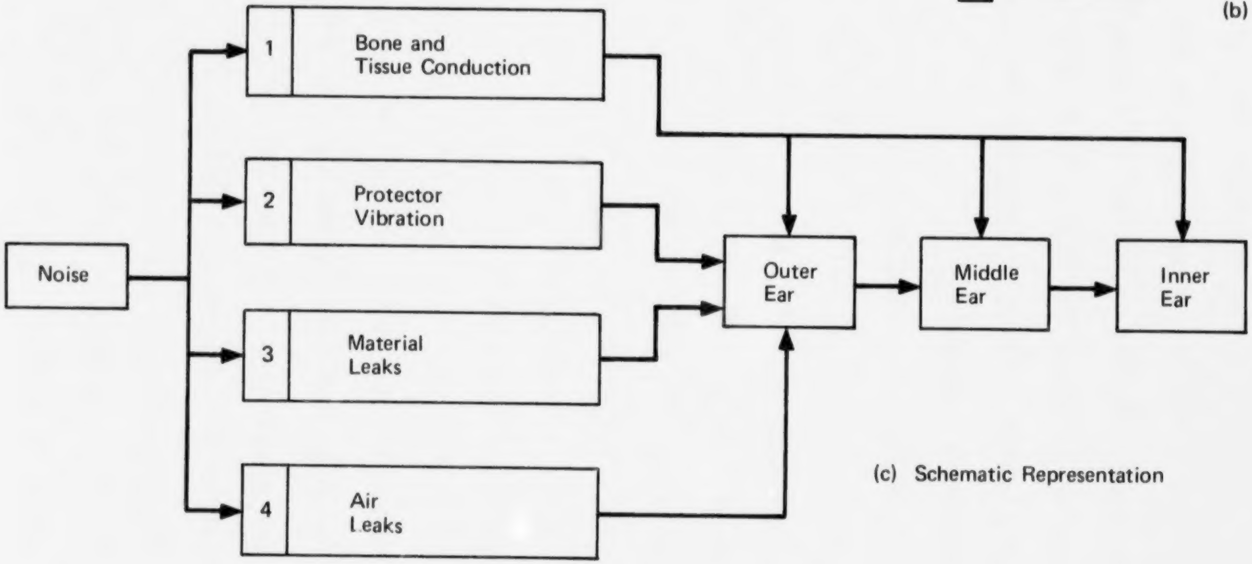
If the device permits no noise leaks through or around it, some noise will reach the inner ear by the first two paths if the noise levels are sufficiently high. The practical limits set by the bone and tissue conduction threshold, and the vibration of the protector itself, vary considerably with the design of the device and the individual's physical structure. However, approximate limits of attenuation for inserts and muffs have been determined and are illustrated in Figure 1.2 [6].

In order to approach these limits, the hearing protector must minimize loss of attenuation due to noise leaks. The following design criteria are useful in accomplishing this goal:


Cartilage and Flesh
Bone
2
3
Eardrum
4
1
2
Cartilage and Flesh
3
Bone
4
1

(a) Earplug

(b) Earmuff


Noise
1
Bone and Tissue Conduction
2
Protector Vibration
3
Material Leaks
4
Air Leaks
Outer Ear
Middle Ear
Inner Ear

(c) Schematic Representation

Figure 1.1. Noise Paths to the Inner Ear

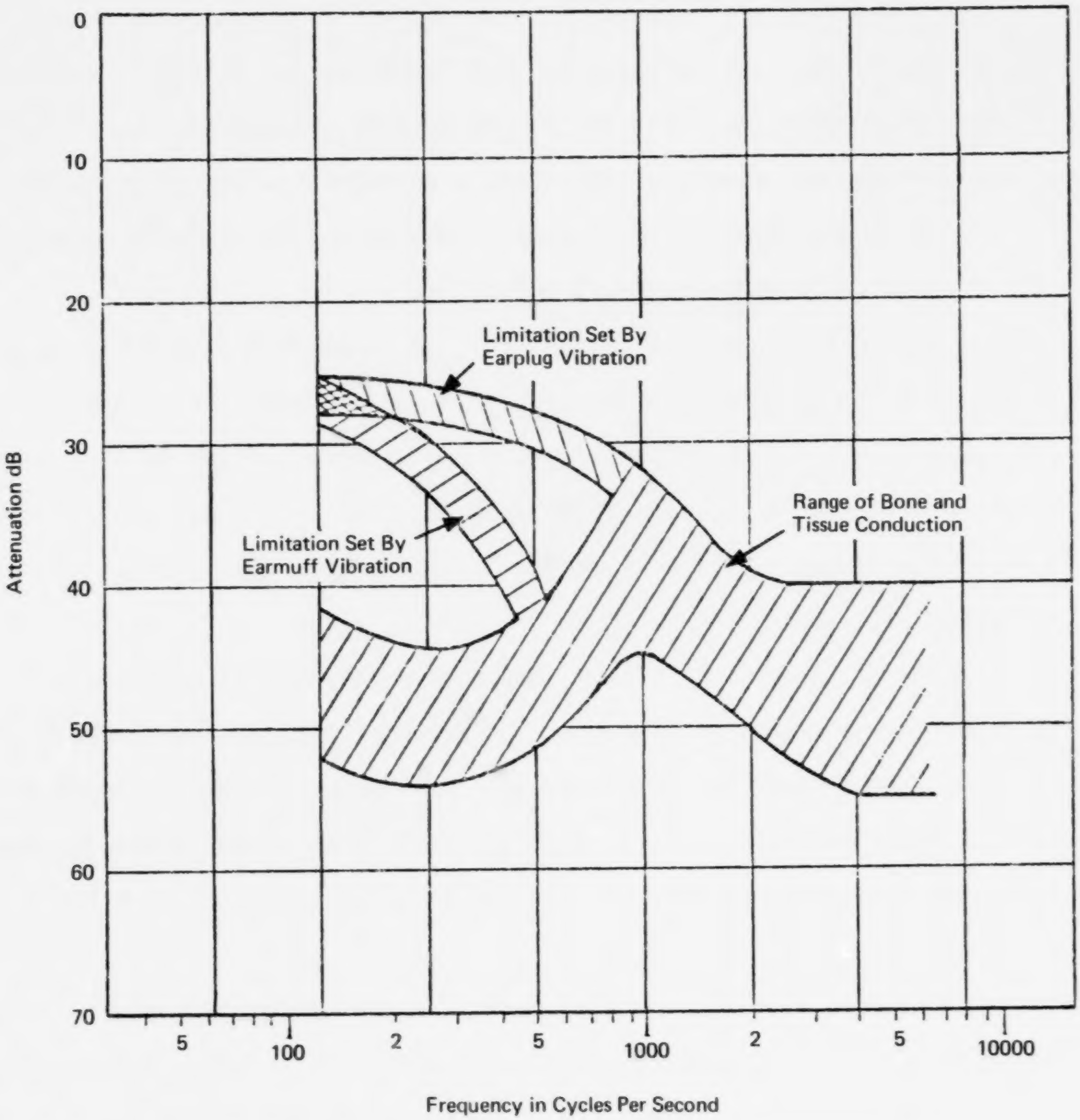


Figure 1.2. Practical Protection Limits for Plugs and Muffs

1. Hearing protectors are generally made of dense material. If it is possible for air to pass through a material, noise will also.
2. Protectors are designed to conform readily to the head or to the ear canal configuration so that an efficient acoustic seal can be achieved, and the device can be worn with reasonable comfort.
3. Protectors generally have a means of support on or about the head or within the ear, or a means of completing the acoustic seal that will minimize protector vibration.

It is interesting to note the relationship between the tradeoffs made by manufacturers of protectors after considering those factors that affect the selection of protectors, and those criteria that affect the design of hearing protectors and the attenuation to be achieved from certain designs; and how those design criteria have been applied to the current generation of hearing protective devices.

Ear muffs use a stiff plastic cup containing sound absorbing material to reduce the transmission of sound. The greater the mass (hence weight) of this cup, the greater is the attenuation available. Weight is a comfort factor, and, therefore, a potential design tradeoff for weight arises between the noise attenuation capability of the device, and the comfort for the wearer.

In a similar example, muff-type devices use headbands as a means of attachment to the head. The greater the pressure that the headband exerts on the head, the better is the seal of the muff with the head. This force is a comfort factor and selection of optimal headband force entails a potential design tradeoff between providing an effective acoustic seal between the muff and the head and minimizing the discomfort for the wearer. The need to accommodate a wide range of head sizes frequently leads to the use of a loose joint where the ear cup meets the headband. This permits alterable headband tension in order to obtain a satisfactory seal with various head shapes. Therefore, there is a design tradeoff between the fitting of relatively few heads perfectly or fitting relatively more heads less perfectly. A suitable material is needed for the ear cup cushions in order to achieve durability, comfort, cleansibility and a good airtight seal. These qualities cannot be expected to be optimized in any one material, consequently there is further potential for tradeoff. The ear cup volume necessary for good low frequency attenuation is balanced against the size limitations of the device so that comfort and maneuverability can be maintained.

The criteria necessary in the design of ear insert devices that perform well in terms of attenuation of noise are balanced against those factors that affect the selection of those devices.

Comfort for the wearer and fit of the device in the ear canal are critical for inserts. A plug must be soft and pliable for comfort and proper fit, yet firm and dense for good noise attenuation. A protector may be designed of relatively low density material and yet provide good noise attenuation by fitting very tightly in the ear. A tight fit is necessary to avoid vibration of the device and subsequent transmission of the noise by the device itself. Therefore, by selecting this type of protector, a comfortable fit may be sacrificed.

TECHNIQUES OF EVALUATING ATTENUATION

A variety of different methods have been tested over the years in an effort to yield meaningful information regarding the attenuation capability of hearing protectors. These techniques may be classified as either subjective or physical (objective). Subjective methods measure a test subject's psychoacoustical responses to noise(s) with and without a protector in place. Physical (objective) methods are those which measure directly the sound pressure level differences developed by a protector placed in the propagation path of a known level of sound. A brief discussion of various methods reported in the literature is presented below. In the "STANDARDIZATION OF ATTENUATION MEASUREMENTS" subsection, close attention is given to the American National Standards Institute standard Z24.22-1957 subjective method which has been widely adopted at this time as the standard method for reporting the performance of most presently available devices.

Subjective Methods

One of the subjective (psychoacoustic) methods, used to evaluate the attenuation potential of protectors, measures the differences in the level of intensity at which the test subject just detects the presence or absence of an audio signal. This is done with the subject's ears unprotected, and then with the subject wearing the protector being tested. This is called the Threshold Shift method. The threshold shift is determined for both ears simultaneously, using pure tones in a free or nearly free sound field.

Narrow and broad band noise have also been used. However, broad band stimuli have been given little attention due to the frequency-dependent nature of attenuation.

A Japanese standard (JISB9904-1598) describes a threshold shift method testing one ear at a time. It requires the subject to press the side of his head against a foam-rubber bordered hole in a loudspeaker box in which the stimulus is presented.

A "masked threshold shift" method has also been used. A miniature transducer is used as a sound source, inserted under an ear muff, and an audio signal is presented to the subject. The intensity level at which the subject is able to detect that signal is determined with high ambient noise present. The same signal is again presented to the subject, but without high ambient noise present. The intensity level at which the signal is detected is determined. The difference in the intensity levels at which the signal was detectable provided a measure of the amount of masking noise excluded by the ear muff.

Another method called loudness balance has been used. The procedure requires the subject to match the loudness of an auditory stimulus perceived while wearing a hearing protector with the loudness of the same stimulus after removing the protector. This method used pure tones in a free field and half-octave band noise in a diffuse field.

The difference in sound pressure level necessary to elicit action of an individual's acoustic reflex (involuntary contraction of muscles of the middle ear in response to acoustic or mechanical stimuli) with and without hearing protectors, has been measured and used to indicate a threshold of hearing shift. Conversely, the difference in temporary threshold shift (TTS) (that elevation in the threshold of hearing which shows a progressive reduction with the passage of time) observed with and without protectors in continuous and impulsive noise environments has been used as an indicator of protector performance.

Articulation or intelligibility testing in a quiet environment, with and without hearing protectors, provides an indication of the degree of degradation of speech by protectors.

The most subjective method is simply to allow an individual to sample the noise reducing effectiveness of a variety of different devices, and to choose the one judged best. Experiments of this nature have shown that unless the attenuation capabilities of the protectors differ considerably, effectiveness ranking by the subjects is not useful.

Physical Methods

Direct physical measurement of hearing protector attenuation is attractive because of the relative simplicity and objectivity of the test as compared to subjective measures. Unfortunately, developing a test fixture which accurately simulates the human ear and surrounding head structure, in terms of acoustic response throughout the audible frequency range, is a difficult task.

At present, a standard method for ear muff measurements exists using a "dummy" head fixture. The method is intended to supplement a subjective test for such purposes as product design and quality control.

A variety of experiments use different means, artificial ears and heads among others, to determine the effectiveness of devices is reducing noise. One system uses a small passive microphone (as opposed to the "masked threshold shift" method which uses a transducer inserted under or through an ear muff. This permits sound pressure level measurements at the ear opening as the protector is worn by human subjects. The attenuation of the protector is determined by comparing the sound pressure level exterior to the muff with that at the interior microphone. This method has produced data agreeing with subjective measurements at middle and high frequencies, but low frequency results diverge by from 3 to 10 decibels. One problem with this method is the placement of the monitoring microphone. Displacements as small as one millimeter can cause changes in the measured sound pressure level at the interior microphone of six decibels or more at high frequencies.

STANDARDIZATION OF ATTENUATION MEASUREMENTS

The need for a standardized method for determining and reporting hearing protector attenuation is apparent when the variety and sensitivity of these measurements are considered.

The American National Standards Institute (ANSI) published the "American Standard Method for the Measurement of the Real-Ear Attenuation of Ear Protectors at Threshold" (ANSI STD Z24.22-1957). The subjective threshold shift method was the only technique which, at that time - 1957 - received sufficient unanimity of expert opinion to be standardized.

The Foreword to this standard states that the original intention was to establish psychological and physical procedures for evaluating hearing protectors, but that the scope was reduced to that of specifying procedures for evaluating the real-ear attenuation of protectors on the basis of auditory thresholds of human observers. The Foreword further states that the standard-writing group was aware of the simplicity of purely physical methods, but felt that comparison of human subjective results to the purely physical methods was questionable. Lastly, the Foreword recommends the need for continued efforts in the field, and recognizes the possibility that there might need to be subsequent revisions to the standard.

The standard specifies that the hearing thresholds of at least ten randomly selected, normal hearing subjects be measured with and without the protector worn. This is to be done on no less than three separate occasions for each individual, at a minimum of nine pure-tone test frequencies (125, 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 cycles per second (Hertz (Hz)). The difference between the thresholds with and without protectors, at each test frequency, is reported as the protector's attenuation characteristics.

This standard, Z24.22-1957, has been used extensively in determining and reporting the attenuation performance of hearing protectors.

The technical community determined that there are several problems with this procedure. First, pure-tone signals are not characteristic of the broad-band noises which are normally encountered in real-world noise environments. Second, the use of threshold-level test tones may not accurately represent performance of protectors in high noise fields. Third, test tones are introduced only from the front position. Attenuation has been observed to vary up to ten decibels with the angle of incidence (the direction from which a sound wave approaches the ear). Finally, the time required to perform this procedure is very lengthy and the test room requirements are strict.

Recognizing the impact of these factors, the U.S. Department of Health, Education and Welfare [7] supported research which was intended to serve as a foundation for revisions to this standard. The most important conclusion of this research was that ". . . . measurement of hearing protector noise attenuation by a threshold shift technique in a diffuse sound field using one-third octave bands of noise as stimuli is a desirable technique and is amenable to attenuation standardization. This technique eliminates the problems associated with pure tone stimuli and a fixed angle of incidence, and also more closely approximates the noise exposure conditions in which hearing protectors are usually worn."

Based on research performed at the Pennsylvania State University, supported by HEW, a revision was approved by the American National Standards Institute in August, 1974 as ANSI STD S3.19-1974. It was also published by the Acoustical Society of America in 1975 as ASA STD 1-1975. This revised standard is titled the "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs." It is this standard that the Agency has adopted as the test method for measuring the noise reducing effectiveness of hearing protectors.

The primary improvements over the previous standard are the use of a diffuse sound field and one-third octave band test tones. The diffuse field eliminates the influence that the angle of incidence has on the attenuation developed by a protector, since diffuse sound impinges randomly from all directions. The diffuse field also facilitates creation of the proper test conditions since a free field is more difficult and costly to produce. The use of one-third octave bands of noise is more realistic than the use of pure tones, and enhances the reproducibility of the test results by reducing the possible variations in protector response due to excitation of resonance in the devices. In ANSI Z24.22-1957, small differences in the absolute frequency of pure tones could cause disproportionately larger differences in the measured attenuation between investigations.

In addition to these revisions to the subjective threshold methodology, a supplemental physical test for ear muff devices is included in the standard. A "dummy head" covered with material that simulates human flesh is specified as a means for obtaining attenuation measurements. However, as stated in the Foreword to the standard, "the physical measurement method is intended for production test and engineering design of ear muffs . . . it is not suitable for earplug testing."

CURRENT STATE-OF-THE-ART OF HEARING PROTECTOR ATTENUATION

Most hearing protector manufacturers have determined the attenuation capability of their devices according to ANSI Z24.22-1957, and report the attenuation value at each discrete test frequency. Some manufacturers have obtained data using the ANSI STD S3.19-1974 methodology, but do not report it because the results generally indicate somewhat less attenuation than the ANSI Z24.22-1957 test. Performance testing is usually conducted by an independent testing laboratory to insure unbiased evaluations.

A report by the National Institute for Occupational Safety and Health, HEW Publication No. (NIOSH) 76-120 [8], contains attenuation data compiled for a wide variety of hearing protectors. NIOSH collected the data in response to a letter survey of manufacturers. NIOSH does not claim that the list of protectors is complete nor does it endorse the data submitted by the manufacturers. The data includes the standard deviation of the measurements at each frequency, and thereby provides an indication of the variability in performance to be expected from protectors with the same model designation.

The data present the current state-of-the-art of hearing protector attenuation. The range of attenuation at the test frequencies is indicated below.

Table 1.1

State-of-the-Art Hearing Protector
Attenuation vs. Frequency
(ANSI STD Z24.22-1957)

Frequency (Hz)	125	250	500	1000	2000	3000	4000	6000	8000
Maximum Attenuation (dB)	33	35	37	46	46	48	50	48	52
Minimum Attenuation (dB)	3	4	5	13	22	28	25	27	19

SIMPLIFIED METHODS OF EXPRESSING HEARING PROTECTOR PERFORMANCE

The attenuation data obtained from the present standardized threshold shift method of rating hearing protector effectiveness (ANSI STD S3.19-1974) is very useful for performance information, provided that it is interpreted and applied correctly. However, it may be difficult for prospective users of a hearing protector to relate octave band attenuation values to the overall protection that would be provided in terms of reduction of the "A"-weighted sound level at the ear. The "A"-weighted sound level (or noise level) in decibels (frequently abbreviated as dB) is a frequency-weighted measure which represents the human response to the sound. This sound level is symbolically represented as "L_A".

Recognition of the difficulty of relating the attenuation data from the ANSI standard to the reduction of noise in terms of L_A, has led to the development of various techniques for rating the effectiveness of hearing protectors by using octave band attenuation data to calculate an estimate of the reduction of noise entering the ear in terms of L_A. These techniques are similar to one another and, generally, trade accuracy for simplicity.

The primary difficulty in estimating the reduction in L_A resides in the fact that performance of hearing protective devices depends upon the frequency spectrum of the noise. Hearing protectors provide different amounts of attenuation at different sound frequencies depending on their design. Therefore, a specific hearing protector, selected because of its ability to attenuate a particular noise with specific dominant frequencies, may provide the wearer with potentially widely different amounts of attenuation of noises with different frequency components because of the differences in attenuation at the various frequencies of interest. Consequently, specifying a constant value of expected attenuation generally does not give a reliable indication of protector performance. Also, there is a significant variation in hearing protector performance observed from individual to individual. This variation is accounted for in the calculation procedures by using the "standard deviation" calculated at each frequency from the 30 measurements required by the standard test procedure.

There are two basic calculation procedures [9] for relating octave band attenuation to L_A attenuation. The distinctions between the procedures lie in the type of data required in the calculations and the relative accuracy of the estimated attenuation value obtained.

Method One

Data Required:	Octave band sound pressure levels at the location where the protector is to be used, at center frequencies of 125, 250, 500, 1000, 2000, 4000, and 8000 hertz (Hz). Hearing protector mean attenuation data for 1/3-octave bands of noise centered at 125, 250, 400, 1000, 2000, 3000, 4000, 6000, 8000 Hz.
Description:	This procedure uses the band attenuation values (test data), adjusted for the observed standard deviation values, to calculate the "A"-weighted octave band levels under the hearing protector (at the ear) for the specified environmental sound levels. Logarithmic addition of these octave band levels yields the effective "A"-weighted sound level at the ear; the difference between this calculated level and the "A"-weighted environmental sound level is the attenuation rating of the protector.
Comments:	This is the more precise method for determining protector effectiveness in an environment with a known frequency spectrum. Attenuation value will vary for different noise spectra but not for different levels of the same noise spectrum.

Method Two

Data Required: Mean values of hearing protector attenuation for 1/3-octave bands of noise centered at 125, 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz.

Description: This procedure also uses the observed band attenuation values, adjusted for standard deviation. It differs from Method One in that a hypothetical environmental sound field is assumed - "Pink" noise with sound pressure level of 100 dB in each octave. The adjusted band attenuation values for the protector are subtracted from the "A"-weighted levels in the corresponding bands to yield the "A"-weighted octave band levels at the ear. The overall "A"-weighted sound level at the ear (logarithmic sum of the band levels) is adjusted upward by 3 dB to account for variations in the spectrum and the result is subtracted from the "C"-weighted environmental noise level to obtain the Noise Reduction Rating (NRR).

Comments: Not as precise as Method One for any specific noise spectrum, but more reliable as a general indication of protector effectiveness in an unknown noise spectrum.

Requires that the noise reduction factor be subtracted from the "C"-weighted sound level to obtain "A"-weighted sound level at the ear.

Noise Reduction Rating is independent of the environmental spectrum to which the user of the hearing protector is exposed.

Method One is the more accurate if the local noise spectrum is known and constant. It requires the use of a Type 1 sound level meter with octave band filters to obtain the needed environmental noise data. The reduction factor is applied to the "A"-weighted level of the noise in the workplace to yield the "A"-weighted level entering the ear.

Method Two provides a reduction rating which, when subtracted from the "C"-weighted sound level of the noise, yields the approximate "A"-weighted sound level entering the ear. This method, developed empirically, requires a 3 dB adjustment factor to allow for the range of environmental noise spectra that may be encountered. A variation on Method Two allows some simplification of the calculation procedure; this is done by providing a tabular format for adding decibels. Use of this table allows addition without resorting to the conventional process of converting to antilogarithms, adding and converting back to decibels. This latter process, however, is accomplished conveniently with a pocket "scientific" calculator.

Both methods use the mean attenuation and standard deviation data determined for a protector by the ANSI STD S3.19-1974 (ASA STD 1-1974) procedure. In each case, the mean attenuation value at each test frequency is adjusted by twice the appropriate standard deviation to insure that 98% (because of the "one-tailed" statistical distribution) of the population that uses hearing protectors realizes at least that amount of noise attenuation.

Method Two is the procedure the Agency adopted in the final rule for calculation of the Noise Reduction Rating that is required for all hearing protectors; either of the methods for adding decibels may be employed.

TABLE 1.2

COMPUTATION OF THE NOISE REDUCTION RATING

Octave Band Center Frequency (Hz)	125	250	500	1000	2000	3000	4000	6000	8000
1 assumed Pink noise (dB)	100	100	100	100	100		100		100
2 "C" weighting corrections (dB)	-.2	0	0	0	-.2		-.8		-3.0
3 unprotected ear "C"-weighted level (dB)	99.8	100	100	100	99.8		99.2		97.0
(The seven logarithmically added "C"-weighted sound pressure levels of Step #3 =107.9 dB)									
4 "A"-weighting corrections (dB)	-16.1	-8.6	-3.2	0	+1.2		+1.0		-1.1
5 unprotected ear "A"-weighted level (step #1-step #4) (dB)	83.9	91.4	96.8	100	101.2		101		98.9
6 average attenuation in dB at frequency	21	22	23	29	41		(43 + 47)/2 =45		(41 + 36)/2 =38.5
7 standard deviation in dB at frequency	3.7 x2 7.4	3.3 x2 6.6	3.8 x2 7.6	4.7 x2 9.4	3.3 x2 6.6		(3.3 + 3.4) =6.7		(6.1 + 6.5) =12.6
8 step #5-(step #6-step #7) develops the protected ear "A" weighted levels (dB)	70.3	76.0	81.4	80.4	66.8		62.7		73.0
(The seven logarithmically added "A"-weighted sound pressure levels of Step #8 using this sample data = 85.1 dB)									

9 NRR = Step #3 - (Step #8 + 3 dB*)
= 107.9 dB - (85.1 dB + 3 dB*)
= 19.8 dB (or 20) (Round values ending in .5 to next lower whole number)
*Adjustment factor for spectral uncertainty

The value for Step #3 is constant. Use logarithmic mathematics to determine the combined value of protected ear levels (Step #8) which is used in Step #9 to exactly derive the NRR.

An alternative method of calculating the NRR is to use the following table as a substitute for logarithmic mathematics to determine the value of Step #8 and thus very closely approximate the NRR.

Difference Between Any Two Sound Pressure Levels Being Combined (dB)	Add This Level to the Higher of the Two Levels (dB)
0 to Less than 1.5	3
1.5 to Less than 4.5	2
4.5 to 9	1
Greater than 9	0

SECTION II

THE HEARING PROTECTOR INDUSTRY

When the Agency published the Advanced Notice of Proposed Rulemaking (ANPRM) in the Federal Register (39 FR 42380), quantitative and qualitative data regarding the hearing protector industry were requested. The Notice of Proposed Rulemaking (NPRM) (42 FR 31730) stated the regulatory approach the Agency intended to pursue when labeling hearing protectors, and solicited comments.

The Agency used information received from the industry association, manufacturers, private citizens and government agencies responding to both the ANPRM and NPRM, and its own research, in order to assess the effect of noise labeling on the hearing protector industry.

The size of the industry and the means it uses to distribute its products are two areas that must be considered when determining the effect that Federally required product labeling will have on an industry.

The Industrial Safety Equipment Association (ISEA) [10], in its response to the ANPRM, estimated that the hearing protector industry was comprised of 25 to 30 major manufacturers. The ISEA claims 17 of these major manufacturers of protectors as members, and stated that these manufacturers represented approximately 80% of the sales volume of all protectors.

The Agency has further determined from safety equipment catalogues, review of the Thomas Register [11], and others, that, in addition to the larger companies, there are small companies that represent themselves as manufacturers of protectors, and "individuals" who produce custom-molded ear plugs for very limited markets.

The chain of distribution used by the hearing protector industry is relatively complex. Distributors generally repackage protectors supplied by manufacturers, and put their own brand names on the packaging. Therefore, a given device may be marketed under several different private labels. For example, a manufacturer who produces a line of ear-muff type protectors may purchase another manufacturer's insert-type protector in order to have a complete line of hearing protectors to offer to customers. Therefore, the manufacturer listed on the label may not (and in the majority of cases does not) actually produce the protectors packaged and marketed under that manufacturer's brand name. The Agency has carefully considered the chain of distribution within the industry in order to assess the economic effects of the provisions of the regulation as they pertain to responsibility for the label, product testing, and for overall compliance with the regulatory requirements.

Another factor that is relevant to the effect of labeling on the industry, based on information supplied by manufacturers, is that hearing protector manufacturers often have supplies used in producing, packaging, and labeling their products on-hand months in advance of the time they actually need them. This is generally the result of lead-time procurements necessary within this industry. The Agency has considered this facet of the industry because making industry on-hand supplies prematurely obsolete by requiring an early effective date for the regulation could cause the economic effect of labeling to be significantly greater than necessary.

Another factor of importance in assessing the potential effect labeling will have on costs to the consumer is the size of the market. Information furnished the Agency by manufacturers, the industry association, and others, indicates that there is no reliable estimate of the total number of hearing protectors manufactured or sold in the United States each year.

However, the Agency has determined from statements made by manufacturers and the industry association that, presently, the major consumption of hearing protectors is in the military and industrial segments of the market, where hearing protectors are used to protect individuals from noise levels in the work situation which can damage hearing permanently. Most of these bulk purchasers are reached either by the manufacturers themselves or by distributors of personal safety equipment.

The present consumption of hearing protectors by single unit purchase is relatively small. The variety of choice is usually limited, with earmuff type devices predominating, since these minimize problems encountered with fit.

ECONOMIC EFFECT OF LABELING

The quantitative and qualitative data requested in the ANPRM relevant to the labeling of hearing protectors included data on the number and types of hearing protectors sold, test methods, existing labeling practices, etc.

The 9 responses to the ANPRM did not provide sufficient data for the Agency to adequately describe the hearing protector industry, and the economic effect of a labeling regulation on it.

Additional requests for production and marketing data (manufacturing costs and processes, marketing procedures, size of the market, numbers and types of protectors manufactured, and market share) were sent to selected manufacturers and distributors. The Agency did this in an attempt to increase the amount of information obtained in response to the ANPRM so it could adequately assess the economic effects of various hearing protector labeling schemes.

The National Institute for Occupational Safety and Health (NIOSH) submitted information listing forty (40) manufacturers and suppliers [HEW Publication (NIOSH) #76-120, September 1975]. Manufacturers and distributors listed in the Thomas Register were also considered for this analysis. In all, the Agency determined that there are approximately seventy (70) manufacturers and distributors who may be affected economically by a labeling regulation.

Additional data were submitted to EPA during the public comment period following publication of the proposed rule (NPRM). These included responses from two of the larger manufacturers of hearing protectors [13, 14]. Their estimates of cost increases per unit were based on promulgation of the rule as it was proposed, which would require that previously bulk-packaged protectors be individually packaged and labeled. A third manufacturer [15] supplied estimates of costs entailed in the preparation of labels.

The Agency has revised its estimates of the costs of this regulation, based in part on this new cost data, and due to other changes which it has deemed appropriate from public comments.

In the absence of an extensive economic data base, the Agency developed what it believes to be a "worst case" estimate of potential industry costs to label hearing protectors. The Agency has assumed that every manufacturer and distributor (wholesale or retail) identified in both the NIOSH publication [6] and the Thomas Register [11], would be affected equally regardless of company size, or contractual agreements with other manufacturers or distributors. Distributors ("manufacturers" as defined in the Noise Control Act) are included within the seventy (70) manufacturers the Agency has determined to comprise the total industry. However, they are not likely to incur the costs of complying with the regulation to the same extent that manufacturers will.

Distributors generally repackage protectors supplied by manufacturers, and put their brand names on the packaging. Therefore, a single device may be marketed under several different private labels.

The final regulation states that a manufacturer's Noise Reduction Rating and Mean Attenuation data may be used when packaging and labeling protectors. Therefore, the only costs likely to be incurred by distributors in complying with the labeling requirements would be those associated with repackaging; not the testing, recordkeeping or reporting costs.

However, since it has been virtually impossible to accurately determine the number of distributors who change their packaging and the average costs associated with such changes, the Agency has developed its best estimate of costs based, in part, on one manufacturer's estimate for label preparation, and the Agency's own assessment of potential labeling costs. The Agency has applied these estimated costs equally to every manufacturer and distributor.

There are two costs to be considered when assessing the economic effect of this regulation: A) first year (start-up) costs; and B) annual costs.

A. FIRST YEAR COSTS

The first year, or start-up, costs to the industry to comply with the Federal labeling requirements for hearing protectors include:

1. Label verification testing
2. Preparation of the labeling verification reports
3. Direct costs of label preparation 1.

1. Label Verification Testing

The cost of testing to develop data to support the values with which manufacturers will label their products, using the required American National Standards Institute Standard S3.19-1974 test procedure, ranges from $1500 to $2000 per test, based on rates quoted to manufacturers by test facilities. These rates include costs for three test runs on each of ten (10) test subjects, and processing and analyzing the resultant data. Each model of hearing protector will need to be tested as well as each position of multi-position devices (e.g., ear muffs).

According to the National Institute for Occupational Safety and Health (HEW Publication (NIOSH) #76-120, Sept. 1975), there are currently 175 models/use positions that should initially be tested (see Table 1.3).

First year costs for labeling verification testing of 175 product test configurations are estimated to be between $262,000 and $350,000 (for per-test costs ranging from $1500 to $2000).

TABLE 1.3

NUMBER OF CURRENT PROTECTOR MODELS AND REQUIRED TEST CONFIGURATIONS

Ear Inserts		
o Premolded		49
o Moldable		7
o Non-Linear		4
		60
Ear Muffs		
o One-position		53
o Two-position	1 x (2)	2
o Three-position	18 x (3)	54
		109
Ear Caps		6
TOTAL REQUIRED TEST CONFIGURATIONS		175

2. Preparation of the Label Verification Reports

The Agency estimates that preparation and reproduction of the label verification reports, of the type required in the regulation, will entail the following workload. This estimate is based on the assumption that manufacturers will average five categories of protectors for which reports will be necessary (using data in NIOSH pub. #76-120).

o Technician	2 days
o Clerical	1 week

Based on comparable Federal Government salaries (Civil Service General Schedule wage scales) the salary/wage costs for a technician (GS-05) and for a clerical worker (GS-04) would be $78 and $181 respectively. An average overhead rate of 110% was assumed based on the values included in contractors' proposals for work recently received by the Agency. Taking into account initial printing of the label verification reports, and 20 cents per page for copying, $100.00 was included for printing/reproduction. Therefore, based on 70 manufacturers, the Agency estimate of the total industry costs associated with the label verification reports is $45,080. (See Table 1.4).

TABLE 1.4

COST OF PREPARATION OF LABELING VERIFICATION REPORTS

o Technical	$ 78
o Clerical	+181
	259
o Overhead at 110%	+285
	544
o Printing/reproduction	+100
o Estimated cost per manufacturer	$644

3. Direct Costs of Label Preparation

The estimated costs for label preparation for the first year include new or revised product graphics, packaging, literature, drafting of labels, and personnel. Of eight replies from hearing protector manufacturers to the ANPRM on the cost of labeling preparation, four were estimated "minimal costs," two said the information was not available, one estimated $0.10 per unit for muff-type devices, and one estimated $1000 for typesetting and artwork. One manufacturer estimated the total costs of label preparation for camera-ready copy and graphics (based on purchasing 100,000 labels) to be

$10,000, of which $7500 were for non-recurring costs. The Agency estimates that the direct cost to the industry for label preparation for the first year would, therefore, not exceed $525,000 ($7500 X 70 manufacturers).

ANNUAL COSTS

The annual costs to the industry to comply with the regulation include compliance audit testing by not more than 15% of the manufacturers in any one year after the first year; label verification testing of new classes of protectors or classes of protectors that have undergone changes which result in decreased noise reducing effectiveness (this is not expected to exceed 10% of the various models of protectors in any one year); and annual administrative costs for reporting and recordkeeping. The Agency's estimate of annual Compliance Audit Testing costs industry-wide is that they will not exceed $21,000 (.15 X 70 X $2000 per test).

Labeling verification testing costs for new products or products changed from a preceding year are not expected to exceed $35,000 (.10 X 175 X $2000).

Annual administrative costs (exclusive of the preparation of labeling verification reports) include costs for maintenance of records and administrative costs of compliance audit testing. The personnel requirements are estimated to be:

o Senior level official - 1 week
o Mid-level official - 2 weeks
o Technical/clerical - 2 weeks

Again, the Agency has, in the absence of industry-furnished data, developed cost estimates based on comparable government wage scales for these positions. These estimated costs are: senior level official (GS-14 - $32,402/yr) approximately $650 for one week; mid level official (GS-12 - $23,100/yr) approximately $888 for 2 weeks; technician/clerical (GS-05 - $10,500/yr) approximately $420 for 2 weeks. Assuming an overhead rate of 110% from previous experience, we estimate that first year costs should not exceed $4,038.

Costs for annual changes to artwork and graphics are estimated at 10% of the $2500 that one manufacturer estimated as recurring graphic expenses; and the cost of preparing label verification reports for those protectors new or changed in the year, is 10% of the first year report preparation costs of $644.

Total industry administrative costs are therefore estimated to be no more than $304,710; see Table 1.5.

TABLE 1.5

TOTAL ANNUAL ADMINISTRATIVE COSTS

o Personnel	
1 senior level	$ 650
1 mid-level	888
1 technician/clerical	420
	1,958
o Overhead at 110%	2,115
	$4,112
o Cost of Preparing Label Verification Reports (10% of $644)	$ 65
o Artwork and Graphics (10% of $2500)	250
	$ 4,427

X 70 manufacturers = $309,890

SUMMARY

Total costs of labeling to the entire industry, based on the "worst case" estimates presented in this analysis, are summarized in Table 1.6. The Agency considers these figures to be the maximum the industry should experience, since both manufacturers and distributors were considered as being affected equally by the labeling requirements. Distributors are not likely to incur costs to the extent assumed in this analysis because, in many cases, they can rely on the data and reports supplied by the producers of the hearing protectors.

TABLE 1.6

TOTAL INDUSTRY COSTS

FIRST YEAR COSTS (Maximum anticipated)	
o Label Verification Testing	$350,000
o Label Preparation	525,000
o Label Verification Reporting	45,080
TOTAL FIRST YEAR COSTS:	$930,080
ANNUAL COSTS	
o Compliance Audit Testing	$ 21,000
o Annual Testing	35,000
o Annual Administrative Costs	309,890
TOTAL ANNUAL COSTS:	$365,890

It is the practice of this industry to pass 100% of production costs through to the ultimate purchaser. We believe this practice will continue.

While the potential percent price increase per pair of protectors is impossible to determine in the absence of market size information, the Agency estimates, based on limited data, that prices may increase between $0.03 and $0.05 per pair of insert devices (if previously bulk-packaged protectors are required to be individually packaged and labeled), and $0.10 for "muff" devices.

The Agency determined from safety equipment catalogues and checks of retail outlets, that the current prices for typical ear insert devices (plugs) range from approximately ten cents per pair of disposable inserts in bulk industrial quantities to as much as seven dollars per pair for individually packaged plugs typically offered to the consumer. Customized plugs can cost as much as thirty dollars per pair but they are the exception in terms of insert devices. Ear-muff type protectors range in price from several dollars when purchased in commercial bulk quantities to approximately fifteen dollars per pair when individually packaged for consumers.

The Department of Defense and several major industries that are affected by the Occupational Safety and Health Administration's (OSHA) rules have been requesting effectiveness data on hearing protectors. Therefore, a majority of the manufacturers already include in their prices the costs of testing protectors to develop effectiveness ratings.

The Agency has had no indication that this labeling rule would impose appreciable burdens on any manufacturer within the hearing protector industry, nor that a regulation in itself would result in any business closures. Our economic analysis did not attempt to predict potential market shifts or potential adverse economic effects that might occur as a result of labeling requirements which would identify some protective devices as being low in effectiveness. Since the intent of labeling under Section 8 of the Noise

Control Act is to provide information to prospective users of noise-producing or noise-reducing products, the Agency believes that any market shifts or other economic effects beyond the direct costs of labeling would be solely related to the competitive nature of the industry. We believe that this industry will adjust itself to reflect purchasers' and users' selections made as the result of any newly available information that may result from noise labeling requirements; not as a result of restrictions that may be imposed by command and control regulations.

REFERENCES FOR INTRODUCTION AND PART I

1. Federal Register, Vol. 39, December 5, 1974, p. 42380.

2. Federal Register, Vol. 42, June 22, 1977, p. 31722.

3. Federal Register, Vol. 42, June 22, 1977, p. 31730.

4. U.S. Department of Health, Education and Welfare: National Institute for Occupational Safety and Health, (NIOSH) Publication Number 79-115.

5. (Figure 1.1(c))
   Michael, Paul L. and Sataloff, Joseph, Hearing Conservation, (Charles C. Thomas, Springfield, Illinois, 1973), p. 291.

6. Michael and Sataloff, 1973, p. 292.

7. Michael, P.L. and Bolka, D.F., An Objective Method for Evaluating Ear Protectors, U.S. Department of Health, Education, and Welfare, 1972.

8. U. S. Department of Health, Education and Welfare: National Institute for Occupational Safety and Health, HEW (NIOSH) Publication Number 76-120.

9. (First three Methods): HEW (NIOSH) Publication Number 76-120.
   (Fourth Method): Environmental Protection Agency, simplification of Method #2 (above), 1978.

10. Wilcher, Frank, for Industrial Safety Equipment Association, Docket entry 74-3-005.

11. Thomas Register, 69th edition, Volume No. 11, G through J.

12. Draft Background Document for the Labeling of Hearing Protectors, EPA 550/9-77-252, April 1977.

13. Plasmed, Inc. Docket 77-5-031.

14. Letter to EPA from Wilson Products Division, ESB Inc.

15. Woods, Thomas J., for Aural Technology Oral Testimony, September 22, 1977, San Francisco, California. Docket entry 77-5-061.

SELECTED BIBLIOGRAPHY FOR PART I

1. Paul L. Michael, Pennsylvania State University, Personal Protective Devices and Hearing Conservation Programs.

2. Donald C. Gasaway, Personal Ear Protection, Aeromedical Review, USAF School of Aerospace Medicine, August 1971.

3. David F. Bolka, Methods of Evaluating the Noise and Pure Tone Attenuation of Hearing Protection, Thesis Abstract, Pennsylvania State University, December 1972.

4. P.S. Veneklasen, Methods of Noise Control: Personal Protection, Noise Control, 1, 29-33, September 1955.

5. U.S. Department of Health, Education, and Welfare, National Institute for Occupational Safety and Health, HEW (NIOSH) Pub. No. 76-120.

6. Acoustical Society of America Standard (American National Standards Institute S3.19-1974) 1-1975, Method for the Measurement of Real Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs.

PART II

DOCKET ANALYSIS

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INTRODUCTION

On June 22, 1977, the Environmental Protection Agency published in the Federal Register a proposed rule (42 FR 31730) [1] to require the labeling of hearing protectors under the authority of Section 8 of the Noise Control Act of 1972, 42 U.S.C. 4907. At the same time, the Agency proposed the general provisions for product noise labeling (42 FR 31722) [2].

At the time of publication, the Agency solicited written comments on the proposed rule on the labeling of hearing protectors, and established a public comment period extending 90 days, to September 20, 1977.

After initial review of the public comment on this proposed regulation, the Agency decided that, in order for the Agency to fully understand the problems the hearing protector industry expressed in their written comments and to clarify certain elements of the proposed rule, a public meeting was in the best public interest. Notice of the meeting was published in the Federal Register on December 3, 1977 (42 FR 61289), and the meeting was held in the Office of Noise Abatement and Control on December 13, 1977 with representatives of Federal agencies, the hearing protector industry, and interested parties attending.

A third opportunity for public comment on the proposed regulation of hearing protectors was the public comment period established for the Notice of Proposed Rulemaking on the General Provisions for product noise labeling. This public comment period ran concurrently with the comment period for hearing protectors. Some comments submitted to the General Provisions referenced the hearing protector proposed regulation, and are included in this analysis.

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This analysis of public submissions to the docket has attempted to identify and group together common issues to facilitate Agency resolution and response. We believe that to the extent possible all substantive issues have been identified, considered and responded to by the Agency.

Each comment referring to the labeling of hearing protectors was given a "docket" number, prefixed by 77-5. Thus, comment 77-5-19 refers to the 19th comment (numbers were assigned according to order in which they were received by the Agency). Comments numbered 77-5-1 through 52 refer to public comments received concerning the NPRM for hearing protectors. Comments numbered 77-5-60 through 69 refer to comments pertinent to the hearing protector proposal but addressed to the docket concerning the general provisions. Comments numbered 77-5-101 through 110 refer to oral statements made at the public meeting on December 13, 1977. For simplicity, only the last 3 digits of the docket numbers are used in this analysis. The number or numbers in parentheses at the end of each comment, or issue raised, refers to the docket number(s) of particular commenter(s).

Appendix A presents a delineation of the issues from each written and oral commenter. Appendix B is an index of all docket submissions which allows one to identify the source of different comments where they are not specifically mentioned in the text.

Section 1: General Issues

1.1 Statutory Authority

Several commenters questioned the Agency's statutory and constitutional authority to proceed with the proposed rule. Other commenters challenged the legal grounds for the noise labeling program in general, as well as specific aspects of the labeling program.

The Industrial Safety Equipment Association (ISEA) (38 and 109) took issue with the proposed rule on various items. ISEA quoted Section 10 of the Administrative Procedures Act [U.S.C. S4907(b)] to support its contention that the proposed rule exceeded the Agency's statutory authority, constituted an abuse of its discretion and was otherwise arbitrary and capricious.

Response:

The Agency maintains that the basis of the proposed rule is the non-discretionary mandate of Section 8 of the Noise Control Act of 1972, which requires, in part, that notice be given to prospective users of products sold wholly or in-part on the basis of their effectiveness in reducing noise; and that the requirements within the proposed rule as to the type of notice to be given are wholly in keeping with EPA's authority, discretion and responsibility to the public.

The proposed rule was developed through extensive discussions with all affected parties. Ample provisions were made to receive substantive written and oral public comment. In view of the careful development of this final rule by considering the comments from, and participation of, affected parties, and the non-discretionary requirement in Section 8 of the Act, the Agency believes that the proposed rule was not capricious or arbitrary.

There is detailed response in later sections of this document to other specific aspects of ISEA contentions in this regard.

1.1.1 Label Content

ISEA (38, 109) felt that Section 8 of the Noise Control Act of 1972 required only a label giving notice of the hearing protector's effectiveness in reducing noise. The requirement that the label contain information such as the EPA logo or the removal prohibition statement was viewed as lacking statutory foundation, for Congress usually expressly included such other information requirements in its Acts.

Response:

The Agency maintains that the Section 8 requirement to give notice of a hearing protector's effectiveness in reducing noise does not limit the Agency from requiring that additional information be available on the label to immediately supplement and give meaning to the notice.

Section 8 of the Act requires that notice be given to a prospective user of the effectiveness of a product in reducing noise. As part of the notice given by the label, the Agency has developed, and will supply to the industry with periodic updating, the comparative range for hearing protectors as a complement to the effectiveness rating on the label. The effectiveness rating, by itself, would not indicate to the prospective user the available range of effectiveness ratings offered by other hearing protectors, nor would it show the effectiveness of a specific protector relative to the noise reducing effectiveness available from other protectors. The comparative range information is intended to give support to the use of the NRR as a means of choosing an adequate hearing protector for a given noise environment. We believe that comparative range information on the label is a key element to the total notice of a protector's noise reducing effectiveness that is supplied by the label.

The Agency addressed in detail, within the General Provisions for Product Noise Labeling, the requirement for the EPA logo on the label. In brief, the appearance of the logo on the label is intended to notify an ultimate purchaser or the prospective user that the label is Federally mandated across the industry, its contents are uniform and that the ratings are credible.

The statement prohibiting removal of the label prior to sale to the ultimate purchaser is based on the prohibition of Section 10(a)(4) of the Act. Removal of the label from a protector before it is sold to the ultimate purchaser is a violation of the Act, and the person who removes the label is subject to a remedial order that the Administrator may issue under Section 11(d) of the Act. This restriction is important for the public to know.

1.1.2 Relationship between General Provisions and Hearing Protectors

ISEA (38,109) stated that the proposed Hearing Protector labeling rule (the proposed Subpart B of the new Part 211 of 40 CFR (as proposed in the NPRM for Product Noise Labeling - General Provisions (42 FR 31722))) was contrary to the preamble of the proposed General Provisions (Subpart A of 40 CFR Part 211) in that administrative, economic, ecological and technical impacts of the program were "substantially detrimental" to the hearing protector industry. The ISEA position was based on the perceived necessary alterations in bulk packaging and the resultant increased costs that the proposed rule would impose on the industry and the consumer if the rule were implemented without change.

Flents Products Company (60) objected to the lack of distinction given to the concurrently proposed Subparts A and B of the new Part 211 of

40 CFR, and the limited opportunity for comment on Subpart B. Bilsom International and others (17, 19, 60) argued that a separate public hearing should be conducted in connection with Subpart B.

Response:

After reviewing comments from ISEA, manufacturers and industry related concerns with respect to packaging and cost issues, the Agency decided to modify the proposed rule to take into account the special circumstances of the packaging and marketing of hearing protectors for various markets. These modifications, discussed in detail in Section 4 of the Regulatory Analysis, minimize the economic impact of the final rule and answer the concerns addressed by ISEA and others.

The Agency maintains that the purposes and contents of both Subpart A and Subpart B of the proposed regulatory category - Product Noise Labeling - of the Code of Federal Regulations [40 CFR Part 211] were clearly distinguished. Subpart A contains the general provisions of the regulatory program applicable to all products for which noise labeling requirements will be developed under the authority of Section 8 of the Act, unless modifications are made in product-specific regulations. Subpart B contains the requirements for the labeling of hearing protective devices and includes any modifications to the general provisions, alternative or additional provisions necessary to adequately regulate hearing protectors.

Concerning the lack of public hearings on this proposed regulation, initially, the Agency did not schedule public hearings for the proposed Hearing Protector regulation, as significant additional public participation was not anticipated. However, in response to several requests for meetings with the Agency from manufacturers of hearing protectors, the Agency held a public meeting on December 13, 1977 in an effort to better understand the effects of the regulation on the industry and to certain elements of the regulation. We believe that the general public and the affected industry have had the opportunity to express their views effectively and completely.

1.2 Interagency Coordination

Four industry commenters cited possible conflict between the proposed rule and other government programs and requirements. Aural Technology (61) expressed a general concern regarding the lack of interagency coordination and the consequent difficulty of satisfying different regulations. ISEA (38 and 109) questioned the compatibility of the proposed regulatory requirements with the National Institute for Occupational Safety and Health (NIOSH) voluntary certification program; and NIOSH (51) commented on several aspects of the proposed requirements. Plasmed, Inc. (31 and 106) asserted that there was conflict between the Department of Defense medical purchase packaging requirements and our labeling requirements.

Response:

From the beginning of the program, the Agency has worked closely with other Federal agencies in an effort to coordinate the hearing protector regulation with other government programs and their requirements. Several relevant agencies, including NIOSH, the Federal Aviation Administration, and the Mining Safety and Health Administration (formerly MESA) either participated in our December, 1977 public meeting on the proposed rules, provided helpful written comments to the public docket, or both.

The Agency has worked closely with representatives of the Department of Defense (Air Force), specifically the Aerospace Medical Research Laboratory at Wright-Patterson Air Force Base. This facility has extensive data on, and knowledge of, hearing protectors, and establishes the specifications for hearing protectors used by the Department of Defense.

The Federal Agencies were also consulted concerning the resolution of issues that developed from public comments to the proposed regulation, and we have received concurrence from all parties.

The Agency worked closely with NIOSH in the development of its requirements for the labeling of hearing protectors to ensure that the two programs would be complementary.

We will continue to coordinate activities with NIOSH to assure that the two programs work together, and produce no conflict or redundancy.

The Agency explored the possibility of conflict with Department of Defense Military Specifications (DOD MIL. SPEC.) on product and product package labeling. DOD MIL. SPEC. experts assured us that there were no apparent conflicts, and that if conflict should develop, the specifications would be changed to incorporate the Agency's regulatory requirements.

1.3 Audience Addressed

A major concern of many manufacturers was the audience addressed by the labeling requirements. The differences between the individual consumer and the industrial market for protectors, and between purchasers and users of protectors, were frequently mentioned. These issue areas are related, since in the industrial market there is often a distinction between purchaser and user, whereas in the consumer market there is frequently no distinction.

Most manufacturers appeared to do more business with the industrial market than with the individual consumer market. While acknowledging the existence of an individual consumer market, the manufacturers felt that the "realities" (the packaging, labeling and use requirements) of the two markets differed. ISEA (38 and 109) asked whether the labeling rule would be made to apply to both industrial and consumer markets and questioned the propriety of such an action. Two manufacturers (40 and 107) recommended that EPA consider different regulations for the industrial and consumer markets.

Bilsom International (44) felt that EPA's regulations confused the identity of the purchaser and user of hearing protectors. They noted that in the industrial market the two are seldom the same: the purchaser is usually the procurement officer or safety engineer of an industry, and not the worker who uses the device. Therefore, the labeling regulations do not represent an effective means for reaching the user of each device. Two manufacturers (1 and 101) felt since the end user is not necessarily the buyer, supplying the NRR to the user would not serve the stated purpose of the program.

The North Carolina Department of Labor (34) doubted that individual consumers would be able to use the NRR to make comparisons, but felt that industrial users would benefit from the NRR. A representative of Reynolds Metals Company (110) felt that employees should have some opportunity to choose their own protectors and recommended a labeling plan which would inform the ultimate user rather than only the industrial buyer. A major characteristic of the industrial market is the prevalence of bulk sales. Since hearing protectors are sold in large quantities to industries, ISEA (38) suggested that the NRR be reported in technical literature and on product cartons rather than on each device and/or its packaging. Bilsom International (44) suggested that there was no need for effectiveness labeling since commercial or industrial buyers do not inspect the product. In general, manufacturers expressed disenchantment over the requirement that devices sold in bulk be treated the same for labeling purposes as devices sold over the counter (38, 46, 106, 101). E-A-R Corporation (104) felt that disposable or semidisposable protectors sold in bulk should be labeled differently than other protectors sold in other ways. A manufacturer of insert type protectors (106) stated that the label was not appropriate for those instances when the device was purchased for swimming protection.

Response:

The major issue raised in these previous comments concerned the impact of the regulations on a major method of marketing hearing protectors: bulk sales. The Agency, because of the many oral and written comments received from hearing protector manufacturers, has given careful and thorough consideration to the production and marketing dynamics of the industry.

The Agency modified the regulation, and now requires the labeling of protectors according to the method by which they are displayed for ultimate purchase or use. Section 4 of this Docket Analysis discusses this labeling method in much greater detail.

Concerning hearing protectors bought by swimmers, the Agency notes that packaging for the device is not directed primarily at the swimmer, but rather implies a broader audience including those persons meant to be addressed by the proposed label. Therefore, if protectors are sold in part on the basis of their effectiveness in reducing noise, they are clearly subject to the labeling requirement.

1.4 Definition of Party Responsible for Compliance

NIOSH (51) stated that the term "manufacturer" is not sufficiently defined in Section 211.2.1 of the proposed rule to clarify the party ultimately responsible for compliance with the labeling regulations. A manufacturer (107) suggested that the last handler of the product before a retail sale, rather than the manufacturer, bear the responsibility for meeting the requirements of label accuracy and visibility at point of ultimate purchase. ISEA (38) also questioned whether these responsibilities would rest with the manufacturer of the device or the packager/distributor. ISEA inquired as to how the Agency planned to handle the matter of the private label manufacturers and their responsibilities.

One manufacturer (106) supported the previous comments by describing the difficulty of determining whether some of his products were destined for the domestic market or for the foreign market, because they were often packaged three or four times. Another manufacturer (107) commented that if he purchased protectors from a manufacturer that had performed the required tests and had provided him with a copy of the test results, his intentions would not be to conduct any additional tests. Does this use of someone else's data satisfy the manufacturer's responsibility for meeting the labeling requirements and, if so, under what conditions? The basic question from these manufacturers is at what point the responsibility for protector and package labeling correctly rests.

Response:

Considering these points, the Agency believes that the statutory definition of "manufacturer" adequately identifies the party responsible for label verification of the protector, for labeling the protector or its packaging, for assuring the accuracy of the information on the label, and for assuring the visibility of the label at the point of sale to the ultimate purchaser or distribution to the prospective user. We have, therefore, simply required that the "manufacturer", as defined in the Act, be identified on the label. The manufacturer packaging the protector for ultimate purchase or use is to be named on the label, is to assure that the information that must accompany the protector as supporting information, and from which the NRR is determined, is provided in the packaging, and is to assure the accuracy of the information on the label. The "manufacturer" who packages and/or distributes the product may elect to either use the information provided by the product "manufacturer" that label verified the protector, or to retest the protector.

Where a device is comprised of component parts or is changed in some way such that the effectiveness may have been altered, the final assembler of the protector is the manufacturer as defined, and acquires the testing responsibility for the purposes of this rule.

Private labeling firms might be employed by hearing protector manufacturers or marketers to produce and/or affix the required labels for the program. Such firms are outside the chain of hearing protector commerce and are charged with no compliance responsibility under the program. In the event of labeling errors or misrepresentations by such label-producing firms, responsibility for label compliance with the Federal labeling requirements remains with the manufacturer that introduces the product into commerce.

1.5 Need for a Public Education Campaign

A private citizen (5), ISEA (38, 109), and an official in the North Carolina Department of Labor (34), directed their comments at the need for consumer education to allow purchaser/users an understanding of various aspects of the labeling program. For example, ISEA (38) recommended that EPA begin a large-scale education program to provide the public with a better understanding of the Noise Reduction Rating scheme.

Response:

The Agency recognizes the need for consumer education if the public is to effectively use the labeling information when selecting products for purchase or use; and intends to provide a public awareness campaign on hearing protectors in order to educate those parties concerned with hearing protection and the provisions of this regulation.

1.6 Comments on Language in the NPRM

1.6.1 Perceived Negative Bias

A major manufacturing company (41) objected to Paragraph 4 of the Notice of Proposed Rulemaking (NPRM) Introduction [1] concerning the efficiency of hearing protective devices. Paragraph 4 states, in part, that the effectiveness of hearing protectors in high noise environments "may be marginal at best." The company cited Air Force testimony at OSHA's Proposed Noise Standard hearing of October 24, 1974, as well as HEW materials and

Army publications, in an attempt to dispel what they perceived as a negative bias against the effectiveness of hearing protectors in the statement.

Response:

The language of the statement referenced by the company was chosen only after Agency consultation with experts in the scientific community, and accurately reflects the situation. The wide range in noise reduction ratings demonstrates the variations in the attenuation capabilities of hearing protective devices. Some protectors might not be adequate for any high noise environments.

A fundamental reason for the uniform rating method and the requirement that the supplemental information report a protector's mean attenuation and standard deviation at the specified testing frequencies is that protectors provide varying amounts of attenuation in varying noise environments, depending on the frequencies present. Therefore, the statement in the NPRM Introduction is correct and appropriate in the context of this regulation.

1.6.2 Impulsive Noise

ISEA (38) took exception to the statement in Section 211.2.4-4(e) that ". . . hearing protectors are recommended for protection against the harmful effects of impulsive noise." ISEA contended that there was no empirical data to support such a statement; they therefore suggested that it be removed.

Response:

After discussions with hearing protector experts and review of ISEA's comment, EPA determined that a modification to the wording was in order.

The first part of the statement now reads "Although hearing protectors can be recommended for protection against the harmful effects of impulsive noise, . . ." This modification renders the statement more accurate while preserving the important concept it intends to convey.

1.7 Exports and Imports

The proposed hearing protector labeling regulation elicited several comments concerning problems associated with the exporting or importing of finished devices or components. One manufacturer (44), especially concerned that the Agency failed to consider the problems of an international company, felt that the costs of a company satisfying different legal requirements in different nations should be reflected in our economic analysis. Another manufacturer (101) was concerned that imported products might be treated somewhat differently than domestic products, depending on the implementation of Section 9 of the Noise Control Act (IMPORTS).

A comment concerning exportation of products was also received. A manufacturer (106) of an insert-type protector which is both exported and sold domestically through brokers stated that it is not possible to know whether a given device will reach a foreign market or remain in the domestic market. Another problem with labeling devices to be exported, he maintained, is that they are often repackaged, as many as four times, by a broker. His company felt that it was virtually impossible to determine if one of these devices was actually destined for export and therefore not subject to the regulations.

Response:

The Agency maintains that those items known to be destined for export will not be required to be labeled for noise-reducing effectiveness. This was proposed in the NPRM and has not been changed. Whatever costs are incurred by a company in testing and labeling protectors that may be exported are costs that cannot be construed as other than necessary to assure compliance of the protector should it not be exported, but entered into commerce within the United States. The cost-impact of this program on firms doing business internationally cannot be a consideration of this rule, for costs and problems associated with compliance of products exported and subject to other country's regulations are the responsibility of the company engaging in that international commerce.

In response to the comment concerning Section 9 (IMPORTS) requirements of the Act, the Agency position is that imported products in violation of the labeling requirements cannot be sold in the United States, regardless of whether separate import regulations have been promulgated. Section 9 simply involves the establishment of an enforcement program that would detect imported products in noncompliance with Subpart B, and its status does not affect the applicability of the labeling requirements to imported products. As noted above in paragraph 1-3, the domestic assembler of foreign-made hearing protector components is considered to be the manufacturer with responsibility for testing the protectors for labeling verification and compliance under the regulation. In the case of exclusively foreign-made devices that are imported and introduced without change into commerce by a domestic firm, the foreign manufacturer shall bear testing responsibility while the domestic marketer shall assume responsibility for label accuracy, visibility, and testing if the test results or testing procedure are suspect.

Concerning the need to know whether a device will be exported or sold domestically, the regulation pertains to "categories" of protective devices in a manufacturer's product line, not the individual protectors. Therefore, if a category of devices is to be marketed at all within the United States, that category needs to be tested and label verified. Individual devices within the category may be exported. The responsibility for packaging and labeling for export lies with the manufacturer that packages the protector(s) for export.

Devices manufactured for the export market exclusively are exempt from the testing and NRR labeling requirements.

1.8 Miscellaneous Remarks

A few problems were mentioned by one or two commenters and could not be easily categorized in one of the major sections of the report. These comments are reported in this sub-section.

Issue:

> One question raised at the public meeting was whether manufacturers' quality control procedures were sufficient to detect if and how content variations between batches of material affect the device's acoustic performance. A manufacturer present at the meeting (106) explained that his firm had no routine acoustical quality control checks.

Response:

One of the parameters for defining "category" for purposes of label verification is the material composition of the protector; therefore, if content variations between batches of material affect the device's acoustical attenuation, the manufacturer has created a new category subject to label verification. It is up to the manufacturer to determine when a change in one of the parameters changes the acoustic attenuation of the device, thus creating a new category.

Issue:

> At least two commenters (26, 31) suggested that the labeling requirements apply to other products used in hearing protection, such as cotton and Swedish wool, even though that might not be their primary function.

Response:

In determining what products will be considered personal hearing protectors for the purposes of this regulation, we rely on the statutory language of Section 8 of the Noise Control Act of 1972. If a device to be used in or about the ear is sold wholly or in part on the basis of its effectiveness in reducing noise entering a person's ear, it is a personal hearing protector under the testing and labeling requirements of this regulation. If, on the other hand, the devices are sold without reference to their noise attenuation potential and are simply adopted for hearing protection purposes on an individual basis by the user, they do not come under the language of Section 8, and are not subject to this regulation. Determining the applicability of the regulation in circumstances such as those described above will occur on a case-by-case basis.

Issue:

> The Forging Industry Association (FIA), (21) which expressed support for the program, felt that EPA should require that

testing results, certified by EPA, be provided by the manufacturer upon request from a customer.

Response:

The major objective of this regulation is to provide the prospective user with valid, reliable and useful information on the effectiveness of personal hearing protectors in attenuating noise. To this end, the Agency is requiring that the composite Noise Reduction Rating (NRR) in decibels, and other essential items, appear prominently on the primary label of a protector's packaging. We are also requiring that the supporting information to the label include the mean attenuation values and standard deviations derived for a category of protectors (obtained according to ANSI STD S3.19-1974), in the table showing the computation of the NRR.

SECTION 2: LABEL CONTENT

Two sections of the proposed regulation, Section 211.2.4-1 (Information content of primary label) and Section 211.2.4-4 (Supporting information), dealt with label content. We received many comments on these sections from both private individuals and the affected industry. A copy of the revised label is shown in Figure 2.1. For analytical purposes, the comments were organized as follows:

- Comparative acoustic information
- Descriptor
- Product and manufacturer identification
- Date of manufacture
- Logo
- Supporting and additional information
- Alternative media

In addition to statements which focused specifically on particular aspects of the proposed requirements for label information, there were also general comments on label content from affected manufacturers (38, 60). Their major concerns were with what they perceived as excessive and redundant information requirements. Noting that Section 8 of the Noise Control Act only requires that the label give notice of the product's "effectiveness" in reducing noise, ISEA (38) thought the inclusion of such items of information as company name, EPA logo, and a prohibition of removal statement (among other things) were beyond EPA's statutory authority. The manufacturers particularly felt that the proposed label requirements for

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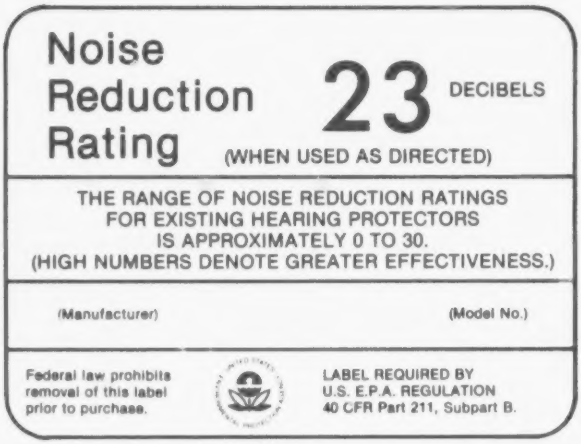

Noise Reduction Rating **23** DECIBELS

(WHEN USED AS DIRECTED)

THE RANGE OF NOISE REDUCTION RATINGS
FOR EXISTING HEARING PROTECTORS
IS APPROXIMATELY 0 TO 30.
(HIGH NUMBERS DENOTE GREATER EFFECTIVENESS.)

(Manufacturer) (Model No.)

Federal law prohibits
removal of this label
prior to purchase.

LABEL REQUIRED BY
U.S. E.P.A. REGULATION
40 CFR Part 211, Subpart B.

Figure 2.1. Revised Label

company name, company location and product identification number were redundant since this information is already provided on the product packaging.

Response:

The Agency addressed questions on our statutory authority to require label information beyond the NRR in Section 1.1.1 above. We maintain that the additional information on the label is necessary to give full meaning to the notice of a protector's effectiveness in reducing noise as required by Section 8 of the Noise Control Act. Items such as the company name and location and product identification number are needed on the label to fix responsibility for the label to facilitate EPA enforcement. The regulation requires the minimum amount of information on the label needed to provide effective notice.

2.1 Comparative Acoustic Information

The criticisms of general label content and the inclusion of information beyond the NRR were also in part criticisms of the inclusion of the comparative acoustic information.

Few comments, however, actually opposed the concept of comparative acoustic range.

There were, however, three manufacturers (38, 40, 44) who commented negatively on the proposed limits of the "0 to 31" range for hearing protectors. They felt that the range should not be tied precisely to the performance of "existing" devices because of future developments which may result in more effective protectors, and therefore require a change in the range values.

ISEA (38) recommended the use of a theoretically "perfect" NRR as an alternative to fixing the upper limit of the range at a specific number. They maintained this would resolve any problems caused by the addition to the market of a new device with an NRR exceeding 31, or by the removal from the market of the best - performing protector thereby lowering the actual upper limit of the range. ISEA also noted that the range was computed from ANSI Z24.22-1957 data, and felt that the Agency should wait until all new ANSI STD S3.19-1974/ASA STD 1-1975 data are collected.

One manufacturer (104) asserted that the range developed by using ANSI S3.19-1974 data would be more on the order of 0 to 35. However another manufacturer (44) disagreed with this statement because their tests, using that standard, showed the best protector would develop a rating of less than 25 dB. Two commenters (40, 44) suggested that the Agency require reporting of an approximate range.

Response:

In order to respond to the valid points made by the commenters, and to take account of any uncertainty that exists regarding the effects of the new standard and new products on the size of the range, EPA has decided to modify the comparative range statement required on the label. The revised range statement reads as follows [Sec. 211.2.4-1(c)]:

> The range of Noise Reduction Ratings for existing hearing protective devices is approximately 0 to 30 (higher numbers denote greater effectiveness).

2.2 Descriptor

The use of a descriptor on the label to communicate information about the effectiveness of hearing protectors in reducing noise received few critical comments. Of greater concern were issues such as the type of descriptor and its name.

2.2.1 Possible Misinterpretations

There were a number of comments about the proposed Noise Reduction Rating (NRR). ISEA (38) expressed concern that the consumer may confuse the meaning of the descriptor and the range, and think that a device with a rating of 29 is effective in 94 percent of all noise exposure (i.e., 29/31). ISEA also feared that exclusive reliance on the NRR would lead potential consumers of hearing protective devices to overlook other important factors such as comfort, durability, or cost, when selecting a protector. With these considerations in mind, ISEA recommended language for the label, or its supporting information, which qualified the meaning of the NRR. ISEA was also concerned that the NRR might not be appropriate for devices which have special application. One private citizen (5), similarly concerned about misinformation, emphasized that the rating scheme should be explained, particularly such characteristics as whether it is linear or logarithmic. Another person (43) simply expressed his opposition to any system which required the consumer to consult other materials to understand the primary label, while a third individual questioned the meaning of the rating number (66).

Response:

The NRR is based on a methodologically sound procedure developed by acknowledged scientific experts in the field of hearing. The hearing protector industry was itself involved in the development of the NRR computation procedure. It is a simple, reliable numerical indicator of a hearing protector's relative effectiveness in attenuating noise entering the ear. The NRR, as with any such indicator, cannot measure all factors affecting the effectiveness of a device. It will not eliminate other factors such as cost, comfort and durability from prospective users' consciousness when selecting the protective device adequate to their needs. Rather, the NRR provides the prospective user with quantified and comparative information through which that person can consider the noise reducing performance of hearing protectors.

The Agency understands the need for the prospective user to comprehend the NRR in order to use it effectively. The public awareness campaign should provide an ultimate purchaser or prospective user with sufficient background on the NRR, which in fact has been developed so that the purchaser or user need not be familiar with the complexities of its calculation, in order to use it as an aid in protector selection.

2.2.2 Single Number Descriptor

The fact that the rating system employs a single-number descriptor drew a few comments. One commentor (49) knowledgeable on hearing protective devices, felt the single-number rating system could provide practical information for comparing the attenuation characteristics of different devices and determining their effectiveness in given noise hazard areas. On the other hand, the DuPont Company (41) claimed that the single number rating should never be used in such a way that it obscures the effectiveness of a device over individual frequencies.

A professor of environmental acoustics (9) implied that the single-number rating was exceedingly difficult to understand, at least if the user wanted to know about the given procedures. He also commented negatively on the choice of the designation of "Noise Reduction Rating", because NRR might be misinterpreted to mean Noise Regulation Reporter, and because increasingly "sound" is being used in the terminology instead of "noise." The suggested alternative was "Sound Level Difference."

Response:

While the Agency recognizes the importance of looking at a protector's attenuation capabilities at different frequencies, it also recognizes the physical and conceptual limitations on the amount of information that can be provided on the primary label. Therefore, we decided to require this kind of data in the supporting information.

Use of any acronym or abbreviation has the problem of possible conflict with any other acronym or abbreviation. Since only a highly specialized audience is familiar with the Noise Regulation Reporter, and since the Noise Reduction Rating (NRR) is an accepted designation in the scientific community, the Agency believes it is justified in retaining the NRR designation as the proper descriptor for hearing protector labeling. Finally, "noise" is a well-accepted term in the scientific community and does not have any debilitating, negative connotations that affect the utility of the rating scheme.

2.2.3 Classification

Another issue relating to the descriptor is whether or not to employ a classification scheme that assigns a symbolic or integer value to a set of personal hearing protectors falling within a certain range of attenuation effectiveness. There existed a difference of opinion on this issue. One commenter (43) emphatically opposed any indirect means of rating the noise reduction capabilities; he desired a descriptor that directly communicated the amount of decibels reduced rather than a system of classes. A scientist for the Civil Aeromedical Institute (FAA) (30) held the opposite view. He believed that a decibel rating could put into competitive disadvantage those devices that offer adequate protection under most noise exposures, but are not listed at the upper end of the NRR range. Other reasons he gave in support of product classes were the "arbitrary" sounding and measurement error that accompanies the decibel rating, the precedent already established by the system of grades of agricultural products, and the ease of comparison afforded by product classes.

Response:

It is the view of the Agency that the positive benefits of the NRR descriptor, including its uniformity, objectivity, precision, and understandability, fully justify its retention for the program over a descriptor system involving product classes. The NRR will provide the ultimate purchaser or prospective user with a precise, numerical indication of the protector's relative attenuation effectiveness. Any classification scheme, however, entails the loss of information since protectors with differing attenuation levels are grouped into the same categories. The result is that better performing devices in the same class as poorer ones are penalized, with little market incentive provided for the manufacturer of the latter devices to improve his product. Furthermore, since the NRR is based on a decibel scale, the descriptor has the advantage of a base of public knowledge about decibels, unlike a protector classification scheme. Finally, using the NRR, and possessing some knowledge of the given noise level in an area, the prospective user could reasonably estimate the effective resultant noise level entering the ear when different protectors are used. Such an estimation would not be feasible if a classification scheme were adopted.

2.3 Product and Manufacturer Identification

From the comments submitted by several manufacturers (51, 38, 106, 107), there appeared to be some confusion about what entity constituted the manufacturer for purposes of identification on the label. One company (61) suggested that the name of the company introducing the product into commerce should be on the label, while the original manufacturer could be identified in the records of the named company.

An industry spokesman (101) commented on protectors that combine helmets or some other head gear, and muff attachments. These two components, he stated, are often marketed together even though they are produced by different manufacturers. Finally, the opinion was expressed that even to include the manufacturer's name and the product number on the label was unnecessary because the information was already on the product or packaging (38).

Response:

As was explained in Section 1.4 of this docket analysis, the manufacturer packaging the protector for sale to the ultimate purchaser or distribution to the prospective user is to be named on the label. EPA will maintain the requirement that the manufacturer's name and product number appear on the label in order to properly fix accountability for the label.

2.4 Date of Manufacture

None of the manufacturers commenting on the proposed inclusion of the date of manufacture were in favor of placing this information on the label. The Industrial Safety Equipment Association (38) asserted that lot control numbers would serve the same purpose as the date of manufacture and that the placement of this information should be left to the discretion of the manufacturer. Another manufacturer (37) also recommended the use of lot numbers.

The E-A-R Corporation (40), while of the opinion that code numbers on bulk packaging would be sufficient identification, stated that the date of manufacture, if required, would be better located on the bulk dispenser box.

Response:

The Agency agrees with the suggestion that manufacturers be allowed to place their own code on the label which would identify a group of protectors and the time period during which they were produced. We have revised the regulation accordingly.

2.5 Logo

There were only two comments about the placement of the EPA logo on the proposed label. Aural Technology, Inc. (61) felt the logo should be placed on the label but stressed that it would seem to be an explicit endorsement by EPA of the validity of the information on the label. The Industrial Safety Equipment Association (38) gave no opinion about the logo per se but said that there was no statutory basis for the requirement of its inclusion, as well as other information, since Section 8 of the Noise Control Act of 1972 requires only a label giving notice of the hearing protector's effectiveness in reducing noise.

Response:

The Agency addressed in detail, within the General Provisions for Product Noise Labeling, the requirement for the EPA logo on the label. In brief, the appearance of the logo on the label is intended to notify an ultimate purchaser or the prospective user that the label is Federally mandated across the industry, its contents are uniform and that the ratings are credible.

2.6 Supporting and Additional Information

This section reports those comments which focused on the regulation's supplemental information requirements or which suggested the inclusion of additional information within the program's scope.

2.6.1 Flexibility

Two manufacturers (40, 44) appeared concerned that the labeling provisions were not flexible enough to meet the industry's legitimate needs. One company (40) suggested that overall flexibility govern the regulation dealing with both the label information and the supporting data. The E-A-R Corporation felt only the NRR need be printed on each package, and the octave band data could be "prominently" lettered on the dispenser or master package (40).

Response:

EPA has, during all stages of the regulatory process, integrated the needs of the industry into the final action. Industry representatives, including spokesmen for large and small hearing protector manufacturers and the relevant trade associations, have been consulted in a variety of forums. However, the Agency believes that the provisions requiring the label and supporting information meet the reasonable interests of industry and the primary goals of the program. In response to E-A-R's suggestion, it should be pointed out that octave band data must be reported only in supporting information and need not appear on the primary label.

2.6.2 Consumer Education

As far as suggestions for additional information are concerned, there were a few individuals who adopted a fairly broad perspective and stressed the need for a consumer education program (24, 109, 51, 29, 38, 34, 5). Several industry commenters pointed out the need to educate the public on how to use the NRR system (29, 51, 38, 109). The Bethlehem Steel Corporation (29) said this information, which could be on the label or in the supplementary information, would help industry to comply with Federal workplace noise exposure regulations. A NIOSH official (51) suggested wording for the supporting explanation of the NRR system.

Response:

EPA's planned public awareness campaign will include an explanation of the descriptor. The details and format of this campaign are being reviewed by the Agency.

2.6.3 Suggested Information for Inclusion

Other kinds of additional information were recommended for inclusion either on the label or in the supporting information.

ISEA and NIOSH representatives (38, 51) emphasized the importance of providing attenuation data on each wearing position for protective devices with headbands (multiposition devices). The ISEA spokesman stated that such information was required so that the wearer does not underestimate the protection offered by the device at different wearing positions.

Instructions on proper use, maintenance, and fit were recommended for inclusion by several commenters (62, 51, 1, 68). A State public official (68) thought a disclaimer was needed to inform purchasers that actual attenuation of devices was affected by improper use; he offered specific language for this purpose. Two commenters (1, 61) addressed the need to inform the consumer about the likely degradation of the attenuation capabilities of hearing protectors.

Three commenters (14, 26, 49) suggested the inclusion of information on the hearing protector's noise reducing capability at individual frequencies. Finally, NIOSH (51) suggested that the supporting information reference methods to predict noise exposure to the user of the protector, when the noise field is being described in different ways (e.g., "A"-weighted level or "C"-weighted level).

Response:

With respect to multiposition devices, the NRR to be put on the label of a hearing protector that uses a headband as its primary means of attachment to the head, and which can be worn in several positions, will be the NRR of the position that yields the lowest effectiveness rating with the position(s) noted on the label. The supplementary information will contain the NRRs for the other wearing position(s) (Section 211.2.4-4(a)).

The Agency recognizes the importance of proper care and fit in achieving the maximum attenuation from the protector. Instructions as to the "proper placement" of a device, as well as a warning on the importance of fit in realizing the stated effectiveness, are required as part of the supplementary information (Section 211.2.4-4(d),(e)). However, the inclusion of information on the "likely" degradation of attenuation is inappropriate at this time because of the lack of useful-life data. The work that the National Institute for Occupational Safety and Health is doing on the actual protection supplied by ear inserts may develop some useful-life data in the future.

Data on sound attenuation values at different frequencies are part of the supporting information (Section 211.2.4-4(a)), as recommended by several commenters.

The ability to use the NRR in different noise fields (e.g., "C" and "A") is explained in the supporting information by showing how to determine the "A"-weighted noise reducing ability of the protector(s) from the "C"-weighted Noise Reduction Rating (NRR).

2.7 Alternative Media

Most industries did not explicitly reject the idea of providing information about hearing protector effectiveness to the public, but felt that there were other ways besides the proposed label to provide consumers with the appropriate data. Bilsom International, Inc. (44) suggested that the information be provided "at a location defined flexibly enough to relate to the product, its package, and the reality of the sales transaction," which was perceived as primarily oriented toward bulk sales to industry. This company and other manufacturers of hearing protectors, many of whom shared Bilsom's criticisms about the label location requirements, recommended alternative ways to supply consumers with the attenuation data.

Four manufacturers (44, 40, 101, 38) felt that the "label" information should be placed in technical and/or sales literature so that the information reaches the proper audience, the industrial consumer. Two of these manufacturers (38, 40) also mentioned another location for the label information that they viewed as appropriate - namely, the dispenser or master cartons containing the insert-type protectors.

Flents Products and E-A-R Corporation (101, 36, 104) both suggested that package inserts might be preferable to labels, either small inserts placed with individual insert protectors or 8 1/2" x 11" sheets of paper contained in larger cartons of several hundred protectors. The cost effectiveness of transmitting information in this manner was thought to be much better than through the labeling program, according to two commenters (101, 106).

Response:

The concerns of these manufacturers are substantially addressed through the Agency's decision to require labeling based on the method of display at the point of sale to the ultimate purchaser, or the point of distribution to the prospective user. This is discussed in detail in Section 4 of this analysis.

SECTION 3: SPECIAL CLAIMS AND EXCEPTIONS

3.1 Exceptions

There were a number of comments on the proposed regulation regarding special claims and exceptions. The NPRM stated that, if a manufacturer believes the NRR is not applicable to a given device, the manufacturer may apply for an exception to certain provisions of the regulation (i.e., test methodology and effectiveness rating). The manufacturers request must offer a "suitable alternate effectiveness rating" for the device, and "be supported by conclusive scientific test data." (Sec. 211.2.5(b)).

Most of the comments dealing with special types of protectors were from two manufacturers, The Norton Company (21, 107) and Aural Technology (39). The Norton Company cited what they viewed to be the advantages of non-linear hearing protectors, expressed concern that these devices may not be testable using ASA STD 1-1975/ANSI S3.19 testing procedures, and felt the resulting NRR of 0 would represent an unfair competitive disadvantage for non-linear protectors. At the same time, they indicated their intention to file for an exception and commented on the related requirement for submitting information on a "suitable alternative effective-rating," supported by "conclusive scientific test data" (Sec. 211.2.5(b)). They noted that the word "suitable" is not defined and maintained that a "suitable" alternative rating system for a device for which the NRR is not an accurate indicator can be independent of and unrelated to the proposed NRR system. They also asserted that the regulation does not define what constitutes "conclusive scientific test data" and suggested language for this purpose.

Aural Technology (39) also requested an exception from the proposed NRR testing system for its vented device, because of the inappropriateness of the test for that particular type of protector. It urged that "an objective evaluation" developed in the Health Sciences Center of the University of Oregon be approved by EPA as a suitable alternative since the proposed subjective method is inappropriate. Otherwise, Aural Technology feared, its vented device would be subjected to an unjustified competitive disadvantage since it would receive an NRR value of 0. In other entries to the docket, Aural Technology supplied supporting data to further recommend adoption of this objective testing alternative.

Norton Company (27) criticized the fact that the exception requirements applied to devices already on the market, which meant that products for which exceptions were being sought could not be sold until an attenuation rating was approved. Specifically, they objected to the second sentence of Section 211.2.5(a), which they felt should be altered to restrict application of the rules to devices not already on the market as of the effective date of the final regulation. The Norton Company (27) commented further that alternative procedures should be established for devices on the market, suggesting that a period of at least a year after the effective date of the rules should be allowed to prepare for the application of an exception ISEA (38) also maintained that there were hearing protectors for which an NRR may not represent the true protective quality of the device.

Response:

The Agency will maintain the provision for special claims and exceptions for those devices for which the manufacturer believes the NRR is inapplicable, since it is not the intent of the Agency to place any special protectors at a competitive disadvantage. EPA will consider these requests for exception on a case-by-case basis, and will notify the manufacturer within thirty (30) days if the exception is approved, if additional data is needed, or if the Agency needs additional time to properly consider the request.

The clear need for uniformity in the testing methodology used in the program demands that a "suitable alternative effectiveness rating" must demonstrate not only scientific validity but also a consensus of use and acceptability in the scientific and industrial communities. Such an acceptable effectiveness rating must display qualities similar to those which led to adoption of the NRR, as for example, standardization, quantification, validity, reliability and understandability. Until a request is presented with rating schemes which, in the Agency's judgment, reflect these qualities, the exception will not be granted.

At present, for example, there exists no widely accepted testing methodology which rates the noise attenuation effectiveness of non-linear protector devices. Since these devices are marketed as hearing protectors, they must be rated with a NRR, until an exception is presented accompanied by a suitable effectiveness rating scheme having a consensus of all non-linear protector manufacturers, which meets the above qualifications. This would allow non-linear devices to be properly rated and compared among themselves.

To set aside the current product line from the requirements of the program pending an exception request, as the Norton Company suggested, would work against the primary goals of the program. The industry will be alloted ample time in the one-year period between the promulgation of the regulation and the effective date to file exception requests for EPA review. It should be noted that only protectors manufactured on or after the effective date of the regulations are subject to its requirements.

The recordkeeping and reporting requirements proposed for special claims of acoustic effectiveness have been reduced. The Agency is not requiring manufacturers to obtain Agency approval of their suggested special claims before presenting them to the public. However, manufacturers wishing to make special claims about the noise reducing effectiveness of their devices, other than the Noise Reduction Rating (NRR), must be prepared to demonstrate the validity of those claims.

3.2 Exemptions

There was also a comment focusing on the particular stage of development of a protection device and the need for an exemption (from the labeling requirements). Bilsom International (1) requested that the regulations not be applicable to new products (prototypes, unmarketed new designs) for a period of twelve months after their entry into the market in order to avoid discouraging product innovation.

Response:

The rule applies to new products (the equitable or legal title of which has never been transferred to an ultimate purchaser) manufactured on or after the stated effective date. Exemptions from the requirements can be requested for prototype devices according to Section 211.1.10 of Subpart A. Products that enter commerce before the effective date of this rule are not required to comply with the labeling requirements of this regulation. The manufacturer may label protectors produced up to 6 months before the effective date of the regulation, as stated in Section 211.1.10-3 (f) of the regulation, if the Agency is allowed to monitor the early label verification testing, and the testing is done with production-line protectors.

SECTION 4: LABEL PLACEMENT, SIZE REQUIREMENTS AND RELATED CONCERNS

Two of the more prominent concerns related to the labeling requirements were label placement and label size. Also discussed in this section are comments pertaining to label color and character or type specification.

4.1 Placement and Type of the Label

The comments concerning label placement were directed mostly toward where to place the label. Commenters indicated confusion over the term "product packaging," as described in Section 211.2.4-3. Wilson Products and Bilsom International (103, 1) requested clarification as to the unit which must be labeled.

Outlining the difficulties of adopting strict labeling standards governing all devices, Flents Products (101) emphasized that a given product is often packaged in several ways, each having its own limitations in terms of labeling (101), while Bilsom International (1, 44) recommended that the regulations be flexible so as to relate to the individual product, its packaging, and the sales environment.

Several comments (1, 36, 38, 61, 101, 106) concerned alternative means of presenting label information, such as sales literature and package inserts. (See also Section 2.7.) E-A-R Corporation (40) urged that only the NRR rating be included on each package and that the remaining information be supplied through other media. The Mine Safety and Health Administration (formerly Mining Enforcement Safety Administration) (16) suggested a permanent NRR on the device itself. J. I. Case Company (32) also had as its first choice a reasonably permanent label on the hearing protector.

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Another manufacturer of protectors (40) pointed out that the printing of information on an individual protector, as opposed to its package, was not practical in terms of hygiene, legibility, or cost effectiveness. The Mine Safety Appliances Company (102) suggested that the embossing of information on individual inserts was inappropriate for monetary reasons. The Industrial Safety Equipment Association and Flents Products (38, 109, 60) requested clarification of the latitude to either affix labels or print them on packages; Flents Products also requested clarification with regard to the acceptability of "hang tags" (4); labels that are affixed to the protector by way of a string.

Response:

The language of Section 211.2.4-3 of the regulation has been modified to clarify the intent of the Agency. It is up to the manufacturer that packages the protector to choose the type of label for his products (i.e., permanent, embossed, stick-on, hang tag, among others). The purpose of the label, as stated in the regulation and in Section 8 of the Act, is to give notice to the prospective users of hearing protectors concerning the noise reducing effectiveness of the product. This is to be accomplished by making the information available before actual sale or use. It is the element of visibility of the label at the point of purchase or use that is of paramount importance. If the label is not visible to the ultimate purchaser or prospective user prior to purchase or use, then the information on the label will be of limited practical value.

Manufacturers may use any labeling means available as long as the labeling requirements are met.

4.2 Industrial vs. Retail Market

Bilsom International and Flents Products (44, 101) asserted that the EPA regulations confuse the product purchaser and the product end-user in those cases where the user-industries purchase protectors in bulk quantities. Label information supplied to the end-user would not serve the purposes of the program acccording to two commenters (1, 101) since the end-user has no control over the purchase decision. Along the same line, a manufacturer (44) stated that the commercial buyer does not inspect the individual product package.

The Industrial Safety Equipment Association (38,109) questioned whether the labeling regulations applied to both the industrial and consumer markets, and how EPA intended to regulate the labeling of devices sold unpackaged in bulk quantities. Two manufacturers (107, 40) felt there should be different labeling requirements for industrial and consumer products.

Flents Products (60, 101) objected to any requirement for labels affixed to individual protectors or their carrying cases when they are sold in bulk, and to the labeling of both boxes and packaging inserts. (See also Section 1.3 for a discussion of industrial vs. retail market.)

Response:

Because of the two markets that hearing protector manufacturers and distributors serve, the Agency is requiring labeling according to the method of presentation of a protector at the point of sale to the ultimate purchaser or distribution to the prospective user. This method, explained in subsection 4.3, labels protectors for both bulk and consumer markets while continuing the industry's present marketing practices and packaging methods.

4.3 Size of the Label

The size of the required label was a major issue. Section 211.2.4-2(a) of the regulation states that the label shall have minimum dimensions of 3.8 centimeters x 5.0 centimeters (approximately 1 1/2" x 2"). Strong recommendations for flexibility in the size requirements were made by Flents Products, the Industrial Safety Equipment Association, and Bilsom International (36, 38, 44). Also noting problems with the label size were the Charles Machine Works, a professor of environmental acoustics, and E-A-R Corporation (37, 9, 40). Commenters (36, 60, 101, 38, 40, 44) used such adjectives as "excessive," "unreasonable," and "impractical" to describe label dimensions which exceed both the size of the product and its package.

Related concerns had to do with costs associated with package redesign (36, 60). Flents Products (36, 101) indicated that hearing protectors should not require more stringent labeling requirements as to size than those required by the Mine Safety and Health Administration (formerly MESA) on respirators. Wilson Products (103) expected no problem with label size for the muff-type protector.

Response:

While packaging changes may result from the requirement that protectors be labeled with a minimum sized label, labels of a size smaller than 3.8 x 5.0 centimeters (cm) (approximately 1 1/2 x 2 inches) with correspondingly smaller print are practically non-informative because of their illegibility. Therefore, the Agency maintains that the label must be no smaller than 3.8 x 5.0 cm.

However, in requiring that the minimum label size be 3.8 x 5.0 cm, the Agency has developed the following labeling criteria based on the means used to display the protector at the point of ultimate purchase or distribution to the prospective user.

(1) If the protector is individually packaged and so displayed at the point of ultimate purchase or distribution to users, the package must be labeled as follows:

  (a) If the "primary panel" of the package, as defined in Section 211.2.3 of the regulation, has dimensions greater than 3.8 x 5.0 cm the label must be presented on the primary panel.

  (b) If the primary panel of the package is equal to or smaller than 3.8 x 5.0 cm, a label at least 3.8 x 5.0 cm must be affixed to to the package by means of a tag.

(2) If the protector is displayed at the point of ultimate sale or distribution to users in a permanent or disposable bulk container or dispenser, even if the protector is individually packaged within the dispenser and labeled as above, the container or dispenser itself must be appropriately labeled. The label must be readily visible to the ultimate purchaser or prospective user.

Labeling of the "Dispenser," as defined in Section 211.2.3 of the regulation, requires that the accompanying protectors NOT be separated from the dispenser before ultimate purchase. Separation is tantamount to removal of the label, which is prohibited by Section 10(a)(4) of the Act.

4.4 Character Type and Color

The Industrial Safety Equipment Association (38) suggested that contrasting colors on the label were unnecessary if the label were legible. They also recommended that choice of size and type be left to the manufacturer for cost-related reasons. E-A-R Corporation (104) submitted a mock-up label which suggests that the required label size cannot accommodate the required type size.

Response:

EPA believes that the consistent requirements for color contrast, minimum size, and type specifications are essential not only to insure the overall legibility of the label but also to provide a uniform label format and appearance. This uniformity is needed to assist the ultimate purchaser or prospective user in identification of the label for comparative purposes.

A misprint in the proposed rules was published in the Federal Register on page 31734, column 3, paragraph 3, line 3; the minimum type size required for Area B of the label should have read "24 point." E-A-R Corporation correctly noted that the printed "42 point" requirements could not be accommodated on the label, given the other area specifications and the minimum label dimensions. However, the Agency has determined that to avoid confusion in the printing of labels, and to be technically accurate in stating the size of the type to be used, we have stated the "type face" sizes for a 3.8 x 5.0 cm label as follows:

Area A - 2.8 millimeters (mm) or 8 point.
Area B - 7.6 mm or 22 point for the Rating.
- 1.7 mm or 5 point for "Decibels".
Area A-B - 1.5 mm or 4 point.
Area C - 1.5 mm or 4 point.
Area D - 0.7 mm or 2 point.
Area E - 0.7 mm or 2 point.

Area F - 0.7 mm or 2 point.

Area H - 0.7 mm or 2 point.

These type face sizes apply to the 3.8 cm x 5.0 cm label; type face sizes for larger labels must be in the same approximate proportion to the label as those specified for the 3.8 cm x 5.0 cm label.

SECTION 5. RATING SCHEME AND TEST METHODOLOGY

5.1 The Noise Reduction Rating (NRR)

The docket contains a number of entries which address overall apsects of the NRR as conceived in the proposed rules. Few commenters objected to the principle of the NRR when it was feasible for the protectors in question, although several persons raised objections to narrow, discrete aspects of the NRR. Alternative ratings or test methodologies were also suggested. (Some of the comments reported here are also discussed in Section 2.2.)

5.1.1 Criticisms of the NRR

Dr. Paul Michael (107), a Pennsylvania State University Professor of Environmental Acoustics (9), sought to clarify language in the NPRM (42 FR 31731, para. 4) [1] by noting that NIOSH does not employ the single-number designation "Noise Reduction Rating" (NRR). He viewed the single-number rating system as needlessly complex, claiming that it emphasizes magnitude rather than reliability of performance. Dr. Michael also pointed out that many Federal agencies, such as the Department of Labor, use the term "sound" rather than the "more pejorative" "noise" whenever possible.

Response:

The NRR required in the regulation is a reliable accepted approach for expressing the attenuation effectiveness of a hearing protector in a readily understandable single-number format. Although the Agency recognizes that there are other characteristics of a protector that also relate to its attenuation performance, we have determined that the NRR is the best available descriptor to give notice to the prospective user of a protector's

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potential effectiveness in reducing noise. For the sake of simplicity and greater understandability in the calculation of the NRR, we have simplified the method of calculation.

In response to the concern about terminology, the Agency views "noise" as unwanted sound. In this respect, "noise" is the appropriate term for use in this regulation, since it is the intent of this regulation to provide information to the prospective user which will assist that person in selecting a device adequate to attenuate the level of unwanted sound.

Issue:

> NIOSH (51) suggested wording for the supporting explanation of the NRR, and urged that the manufacturer be required to provide the exact mean attenuation and standard deviation on which the labeled NRR is based.

Response:

The regulation requires that the mean attenuation and standard deviation for a category of protectors be reported in the supporting information included in the packaging.

Issue:

> A spokesman for the Australian Department of Health (47) suggested that EPA re-examine the need for the 3 dB "spectrum" correction in the NRR calculation since it might not be imperative for adequate protection.

Response:

The "spectrum" correction is based on firm data originating from the scientific community concerned with hearing protection. Its appropriateness for the goals of the program can be readily documented through scientific evidence. EPA has therefore determined that it should be retained.

Issue:

The DuPont Company (41) recommended comparison testing of one-third octave band measurements and standard octave band measurements to determine if the costly one-third octave band method is needed for the program.

Response:

The use of the one-third octave band method was adopted after close consultation with the protector industry community. This methodology is fully accepted in both scientific and industrial communities, and is essential for evaluating protector effectiveness at various frequencies.

Issue: Another commenter (30) particularly commended EPA's selection of the method of the mean attenuation value minus two standard deviations, and included a paper he wrote pointing out the value of such an approach. However, an official of the Mine Safety and Health Administration (formerly MESA) (16) felt that the NPRM was incorrect in stating that the subtraction of two standard deviations from the mean attenuation values "assures applicability of the attenuation estimates to 98 percent of the population." He claimed that the confidence level would be 95 percent.

Response:

Since the calculation is based on a one-tailed statistical test in that the values exceeding the upper confidence limits are safe, the 98 percent figure is the correct one. To clarify the meaning of the statement, it should state that 98 percent of the population will be at or above the stated value and therefore on the "safe" side of the rating.

5.1.2 Other Purchase Considerations

ISEA (38) feared that exclusive emphasis on the NRR could lead consumers to overlook other important factors such as comfort, cost, durability and compatibility with other protective equipment and suggested that certain language be added to the label, master carton, or sales literature which would encourage use of protector selection criteria in addition to the NRR.

A spokesman for the Australian Department of Health (47) expressed the opinion that, under the proposed NRR, the user would be overprotected with unnecessarily heavy and uncomfortable hearing protectors.

Response:

The NRR--far from replacing other factors such as comfort, cost and durability that figure into the selection of a protector for a particular situation--augments their use by providing an objective, reliable source of information in the most vital area of protector performance, i.e., its actual effectiveness in reducing noise. Furthermore, the regulation does not restrict manufacturers from including in their marketing literature, packaging etc., any other factural information.

The Agency believes that the requirements of this regulation are unlikely to cause the prospective user to be burdened with unnecessarily cumbersome protectors. In the protector industry, comfort and fit of the devices are afforded strong emphasis in product development. Better performing protectors are not necessarily less wearable or comfortable than other protectors.

5.1.3 Objective Test Methods

The ISEA (38) suggested that physical measurement methods should not be applied to the evaluation of hearing protector performance until adequate procedures are fully developed.

Plasmed (31) urged EPA to develop a less costly objective test method to replace the proposed subjective test. However, other commenters expressed reservations about objective test methodologies for hearing protectors. One manufacturer (1) pointed out the limitations of objective testing, while a second commenter (101) asserted that no satisfactory or reliable objective tests for insert protectors exist. In response to questions about the possibility of using an objective test as a screening device to identify significant labeling inaccuracies, an E-A-R Corporation representative (104) noted that tests conducted by his firm indicated no correlation between a given decibel change in an objective test using an artificial "ear" and a given decibel change measured in a standard subjective test. A Norton Company official (108) suggested that artificial objective testing is inappropriate for purposes other than quality control.

Response:

There is a consensus within the scientific and industrial segments of the protector community that no suitable objective test of protector attenuation effectiveness is currently available for general use. Should the industry find a correlation between the results of the required methodology and some objective test, and wish to use the objective test internally for its own purposes, the Agency would have no objections. The American National Standards Institute Standard S3.19-1974 procedure remains the required method for compliance with the testing and labeling requirements of the regulation. If a breakthrough should occur, such that a national or international standard is developed for an objective method that permits reliable testing of all hearing protectors to the accuracy of the present subjective test method, the Agency will consider it as a candidate to replace the present method.

5.1.4 Alternative Approaches

Eleven commenters offered suggestions or observations on possible alternative approaches to the proposed NRR. A NIOSH official (51) pointed out that his agency's certification program takes into account other important performance characteristics of protectors beyond those reflected in the NRR, and the DuPont Company (41) suggested that EPA adopt the original NIOSH rating system contained in Section I of Criteria for a Recommended Standard in Occupational Exposure to Noise (NIOSH, 1972).

A citizen (64) cited a possible alternative to the NRR contained in the following publication: Selection Guide to Hearing Protectors for Use on Firing Ranges, National Institute of Law Enforcement and Criminal Justice, LEAA, April 1976. He noted that its effectiveness rating number ranged from 6 to 47.

An expert in the area of hearing protection devices (30) objected to the use of the decibel-number NRR instead of a rating system using product classes. To demonstrate the possibility of a classification scheme he submitted a paper describing his Protector-Attenuation Rating (P-AR). He mentioned that the P-AR takes into account three major factors determining protector effectiveness and arrays protectors in six classes based on the difference between a protector's score and the mean attenuation in units of standard deviation.

Response:

As previously explained, the Agency has given due consideration to other performance characteristics and rating schemes, and has adopted the composite NRR for its qualities of reliability, validity, ease of quantification and usefulness.

The reasons for not choosing a classification scheme were discussed in Section 2.2. Briefly, the Agency has determined that a product classification scheme is disadvantaged by its inherent loss of information in comparison with the accepted precision of the NRR as adopted.

5.2 Selected Standard

EPA's selected standard for determining the value of the sound attenuation level, the American National Institute Standard (ANSI STD) S3.19-1974, "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs", attracted a significant number of comments which centered on questions of the variability of test results under the standard, the use of C-weighting, fitting considerations and possible alternative standards.

5.2.1. Miscellaneous Comments

A Professor of Environmental Acoustics at Pennsylvania State University (9) suggested the typographic correction from Z22.540-1957 to ANSI Z24.22-1957 in Section 211.2.3 (b) and (c). Another commenter (3) noted that the ASA STD 1-1975 (ANSI STD S3.19-1974) calls for a band force report but fails to specify how a hardhat hearing protector attachment can be measured for force.

Response:

The Agency gave careful consideration to a comment that the test method requires a report of the force that the headband procedures, and its effect on the noise reducing effectiveness of protectors that use headbands as their principal means of attachment. The test method does not state how the data is to be derived for hardhat hearing protectors. EPA concluded, after conferring with technical experts, that the "band force", as derived in the standard, was designed to measure only "muff" type protectors that actually employ a band as the means of clamping the protectors to the user's head. Hearing protectors combined with hardhats do not normally depend on a headband for clamping force. However, until another measurement method is devised that adequately measures the clamping procedure used by hardhat protectors and relates this to their noise reduction rating, the mean attenuation levels at the test frequencies and the NRRs for this type of protective device must be derived according to the designated measurement method. When a validated procedure is available, an exception may be requested, and the Agency will review the request.

5.2.2 "C" vs. "A" Weighting

While Flents Products (4) had no serious objections to the selected standard, it did urge EPA to exercise caution in the use of this relatively new and unproven procedure. E-A-R Corporation (104) pointed out that certain test results for a given protector differed between the old and new standard. E-A-R estimated that the likely range of the NRR under ANSI S3.19-1974 would be an approximate range of zero to 30 or 35.

The requirement for "C"-weighting under the selected standard drew comment from four respondents (9, 16, 38, 41). Taking exception to page 31731, Col. 1, Para. 2, Lines 1-5 of the proposed rules, Dr. Paul Michael (9) argued that "A"-weighting does not "approximate the human threshold of hearing curve" while "C"-weighting is "relatively unweighted (as stated in the regulations)" only at the center frequencies. Three commenters, including the Mine Safety and Health Administration (MSHA) (formerly MESA)(16), reflected concern about the NRR's reliance on "C"-weighting and generally preferred "A"-weighting, partially because of the "A" weighted sound level meters commonly used in industry. The comment by the MSHA expressed a concern about the implied need to measure the "C"-weighted noise level in the workplace in order to calculate the "A"-weighted noise level entering the ear of a hearing protector user, if the protector is rated by a rating factor derived from "C"-weighted noise.

Response:

EPA consulted with representatives of the industry and of the scientific community and has determined that the Noise Reduction Rating (NRR), derived from a hypothetical noise level that is "C"-weighted, will provide the best descriptor currently available for the uniform rating of hearing protectors for use in all noise enviornments.

The MSHA concern is pertinent if the environmental noise spectrum is dominated by low frequencies (below 500 Hz). However, in many industrial noise environments, the spectrum is not dominated by low frequencies, and the "A"-weighted noise level closely approximates the "C"-weighted level; consequently, subtracting the NRR from the "A"-weighted environmental noise level yields a good approximation to the "A"-weighted level entering the user's ear, and a "C"-weighted measurement is not essential.

It also is pertinent that, at high noise levels, the spectral response of the ear is similar to "C"-weighting, so that the degree of protection afforded the user is indicated reliably by the NRR which is the difference between the "C"-weighted noise level of the environment and the "A"-weighted noise level at the ear less 3 dB for spectral uncertainty.

5.2.3 Proper and "Best" Fit

Many comments addressed the issue of the difficulty of achieving the proper fit and wearing position for ear protectors, which affects a major reduction in real attenuation (versus the attenuation values yielded under test conditions with the selected standard). This raises the question of whether or not the real-life environment should be sought in the test conditions outlined in the standards. NIOSH (51 and 105) reported that its research indicated that protectors provide 50 to 65 percent less attenuation in actual use than under laboratory conditions, probably because of improper or variable fit and improper use of the devices by the field-tested subjects. Four other individuals (62, 68, 69, 108) offered similar observations on the effects of improper fit and individual subject variability in protection afforded by a device.

Dr. Michael (9) contended that all protector sizes should simply be available for the ten test subjects (rather than randomly selecting the test subjects and expecting the selected people to require all sizes of the protector under testing).

A comment was made about the type of fit permitted in the testing, with one manufacturer claiming that results from "best fit" subjects should not be used for labeling or advertising because of the potential for variability between subjects (18). This individual advocated complete randomness in the choice of test subjects and, most importantly, the reporting of all test results.

Response:

EPA recognizes the problem of the variation between attenuation test values obtained under laboratory conditions and those obtained in the field. This variation can be explained through individual wearing differences and through improper use and fit of the devices in the field. Therefore, the regulations require that the supporting information contain a statement on the negative effects of improper fit on the attenuation performance of protectors, as well as instructions on proper fitting of the device.

The Agency, following discussions with appropriate experts and a thorough review of the issue, agrees with Dr. Michael that having all sizes of the protector available for the ten test subjects reasonably fulfills the requirement of randomness. The requirement at Section 211.2.10-2(c) has been modified accordingly.

5.2.4 Alternative Standards

Three commenters made remarks related to possible alternative standards. Bilsom International (1) called for a testing standard that reflects both noise reduction and wearability factors. Aural Technology (7) submitted comments on the selected standard in support of its contention that its vented device should be tested under an alternative standard developed at the University of Oregon. An agency of the Government of Austria (22) requested the reason why EPA did not adopt International Standards Organization (ISO) Standard 4869 for the program.

Response:

The Agency is aware of no testing standard that objectively quantifies wearability of hearing protectors that might be adopted for this regulation. The acceptability of alternative standards through exceptions, such as that suggested by Aural Technology, is discussed in detail in Section 3 of this docket analysis. In response to the inquiry from the Government of Austria, the Agency decided that ANSI S3.19-1974 was preferable to the ISO Standard 4869 based on the evaluation obtained from the scientific community. It should be noted that ISO 4869 was in fact developed from the chosen ANSI S3.19 standard.

The Agency tries to use measurement standards from voluntary standard-setting organizations that have been developed, validated and are in use.

The Agency encourages the development of improved subjective and objective test methodologies. Procedures that have been demonstrated to correlate with the prescribed procedure should be submitted to the Agency for consideration as alternate methodologies or replacements to the procedure specified under Section 211.2.5 of the regulation.

5.3 Laboratory Facilities

There were numerous comments, in both the written submissions to the docket and at the public meeting on December 13, 1977, about the laboratory facilities that would be needed to conduct the testing. Three major concerns reflected in those comments were the availability of laboratories capable of performing the required test, the possibility of obtaining biased results from some testing firms, and the variability in test results between different laboratories.

5.3.1 Availability of Testing Laboratories

Representatives of several affected manufacturers (102, 101, 38) questioned whether or not there were sufficient laboratories available to permit nationwide implementation of the program. One commenter (101) reported that there were no more than three laboratories currently able to perform the required tests, while another commenter (102) stated that only one of the three laboratories found to do psychoacoustic testing did contract work for manufacturers. An ISEA spokesman (38) asked if the Agency knew the number of laboratories presently equipped to conduct the ANSI S3.19-1974 test.

A related concern of manufacturers was the possibility of lengthy delays in testing due to excessive demands placed upon the few laboratories thought to be capable of performing the tests. Because of this limited capacity, one commenter (101) thought the six-month period from promulgation of the regulation to the effective date should be extended to no less than twelve months and preferably to eighteen months.

Response:

The Agency consulted with experts in the field of hearing protection and laboratory management and was assured that adequate facilities would exist given adequate lead time before the effective date of the regulation.

The Agency further determined that those laboratories presently capable of testing hearing protectors according to the required test method are: the Pennsylvania State University (Environmental Acoustics Laboratory, State College, PA), the Worcester Polytechnic Institute (Worcester, MA), the U.S. Naval Air Station, (Pensacola, FL), the U.S. Aviation Center (Ft. Rucker, AL), and the National Institute for Occupational Safety and Health (Morgantown, WV).

Partly in order to allow greater availability of laboratory facilities, the Agency is requiring the regulation to be effective one (1) year from promulgation of the final rule. This should be ample time to perform the initial product testing required.

5.3.2 Possibility of Biased Results

Several comments (51, 62, 101) dealt with the potential for biased test data resulting from manufacturers using their own laboratory facilities or working in collaboration with test firms. One commenter (62) was especially concerned about the possibility of fraudulent activities practiced by test labs (62). A spokesman for NIOSH (51) said that his agency's experience with using test facilities that are either manufacturer-owned, or manufacturer-selected, indicated that both approaches result in inadequate enforcement. He suggested EPA rely on NIOSH test data once their certification program is established. On the other hand, one manufacturer (40) thought that each industry should be allowed to choose the lab it uses for compliance audit testing.

Response:

The enforcement procedures within this regulation are specifically designed to effectively handle cases of improper labeling. The provisions for monitoring the accuracy of test results and of labeled values, the possibility of Federally-supervised compliance audit testing, and the potential for recall or relabel are considered adequate deterrents to testing fraud. However, should the Agency receive evidence of widespread improprieties with respect to product testing, it will consider alternative measures.

5.3.3 Test Variability

Test variability between different laboratories was a concern mentioned by three commenters (44, 103, 104). One manufacturer (44) felt that the regulations do not recognize the influence of laboratory conditions on test results, and therefore it would be unfair to hold manufacturers liable for these limitations. A representative of the E-A-R Corporation (104), also commenting on variability between laboratories, recommended that any retest be done at the same laboratory which did the original testing, assuming that the facility was on a government-certified list of laboratories. He also suggested that, if the new mean was not more than one standard deviation lower than the prior reported mean, the product should be judged to be in compliance.

Response:

The responsible parties must take into account testing variability and the influence of laboratory conditions when reporting test results or labeling products. Some variation because of testing conditions enters into any scientific measurement procedure.

However, the Agency concluded, after conferring with both private and government testing laboratory technical experts, that "experimenter fit", (i.e., the hearing protector is fitted to the test subject by the experimenter) rather than "subject fit" (where the test subjects fit themselves with the protectors) should be required.

While "subject fit" results in a more subjective rating of a protector, it also produces values of noise attenuation that spread much more widely about the "mean" (average) attenuation value for a test frequency. Consequently, enforcement procedures based on a test using "subject fit" would have to allow greater variability in the values derived from the test. This dispersion of values about the "mean" reduces the possibility of reproducing the attenuation values from test-to-test, and thus the test is less strictly enforceable.

"Experimenter fit", however, ensures greater consistency in the "fit" of the protector to all subjects, which tends to reduce the test-to-test variability.

We have examined the potential for variability in the test between facilities, and agree that there may be variations in measured attenuation from facility to facility as a result of slight differences in the physical facilities or in the way the facility implements the test. However, because of the modification of the test procedure to require "experimenter fit", we believe these variations to be small. Furthermore, the procedure, of itself, will reduce variations between test facilities because of the thirty (30) tests required during labeling verification to obtain a single NRR for a category of protectors. The consensus of technical experts was that manufacturers will take possible variations between test facilities into account in designating NRRs for their protectors.

SECTION 6: ENFORCEMENT

The label verification and enforcement scheme of the program drew a wide variety of comments, many of them specific and technical. A few entries did address the general enforcement approach. The Forging Industry Association (FIA) (26) stated a preference for voluntary compliance by the hearing protector manufacturers, and a state government official from North Carolina (34) suggested that EPA provide testing as a service rather than requiring it by regulation. Industry spokesmen for ISEA (38) and E-A-R (40), expressed the opinion that the compliance system creates a gambling situation for the manufacturer, in that he is forced to calculate the degree of risk he is willing to take in assigning his product an NRR.

Response:

None needed.

6.1 Label Verification

6.1.1 General Issues

One manufacturer (31) asked if separate label verification tests would have to be conducted for each of the firm's customers, resulting in prohibitive testing costs. Another manufacturer (44) expressed opposition to what he perceived as a requirement for the pre-approval of labels in 211.2.10-3, viewing it as a costly delay in the distribution of products.

The Industrial Safety Equipment Association (ISEA) (38) concurred with EPA's decision that only production model protectors be required to undergo verification testing, but also suggested that the requirement for samples of products for compliance audit testing in Section 211.2.12-1(c)(5) should be consistent with accepted practices for the type of device being tested. They recommended the testing of ten circumaural devices and possibly 30 pairs in the case of ear inserts.

A hearing protector manufacturer (106) wondered if both the manufacturer and distributor would each have to conduct separate tests. The DuPont Company (41) recommended that only new products be subject to the requirements of the program.

Response:

Separate label verification tests are not required for each of a firm's customers. Label verification is the testing of categories of hearing protectors to determine their effectiveness in reducing noise--the NRR. Protectors introduced into commerce must be labeled with the NRR for the category to which they belong. The manner of distribution of protectors is not pertinent to the rating of protectors for effectiveness.

There is no requirement for advance approval of compliance labels under this regulation.

The manufacturer who physically assembles or produces the hearing protector must satisfy the label verification test requirements. The manufacturer who packages the device for display at the point of sale to an ultimate purchaser or distribution to a prospective user is responsible for all elements related to the labeling of the device. It is expected that a formal chain of liability will be developed between manufacturers of protectors and those who package and market the device.

6.1.2 Annual Testing

Several commenters focused on the requirement that labeling verification occur at the beginning of each calendar year, subject to certain exceptions. Another commenter (9) noted that the concept of once-a-year testing would impose heavy burdens on manufacturers. ISEA (38) questioned whether the wording of Section 211.2.10-8 could be construed to allow the Administrator to require annual testing for any chosen protector. ISEA (38, 109) also inquired about the conditions under which the previous year's label verification data would not be accepted for the current year's production. Bilsom (44) recommended that label verification be required only if there is a negative change in the level of protection (from a device) rather than on an annual basis.

Response:

The proposed annual Label Verification (LV) test requirement has been modified to require a manufacturer to test each category of protector once and retest only where changes are made to the category which could affect its noise attenuation. Newly introduced categories, of course, must be tested and labeled in accordance with the regulation.

The Agency's decision to drop the annual test requirement was based, in part, on its plan to conduct tests on products selected "off-the-shelf" to determine whether they are labeled correctly. Where they are not, we would follow-up with an enforcement action to remedy the situation.

6.2 Compliance Audit Testing (CAT)

6.2.1 Circumstances Leading to CAT

A number of commenters inquired about the circumstances under which EPA would mandate compliance audit testing. Three spokesmen for the hearing protector industry (38, 40, 61) felt that EPA should not order compliance audit testing in the absence of evidence of probable cause that a manufacturer had violated the labeling regulations. ISEA (38) asked EPA to spell out clearly the parameters leading to a compliance audit testing order. The Tasco Corporation (3) requested clarification of whether the compliance audit testing itself would be performed by a government agency or each manufacturer.

Response:

The Act does not require that the Agency have probable cause before issuing a Compliance Audit Test (CAT) order. This authority will not be limited by regulation. In most cases, however, the Agency would issue compliance audit test requests where there is reason to believe there is noncompliance, but it reserves the right to issue requests on a random basis.

The Agency expects to conduct tests of the effectiveness of all categories of protectors on the market, using the designated test methodology, through a laboratory contracted to randomly or selectively, at our direction, test hearing protectors. This would test all manufacturers' products at least once every two years. Those manufacturers perceived by the Agency to be having a problem meeting their labeled values may then be required to perform Compliance Audit Tests more often than others.

Specific criteria have not been developed to select manufacturers for testing in any particular order.

6.2.2 Time and Cost Requirements

ISEA (38) had other objections concerning the section on Compliance Audit Testing (211.2.12). The Association objected to the 24-hour requirement [Section 211.2.12-1(e)(3)] for shipping devices to a testing facility as unreasonable and suggested the period be extended to at least one week. ISEA also proposed that a minimum of 30 days be granted for completion of compliance audit tests with provision for automatic extensions if the laboratory is unable to meet established guidelines.

Two other commenters (34, 44) suggested that EPA and not the manufacturer bear the cost burden of compliance audit testing.

ISEA (38) and the E-A-R Corporation (40) challenged the requirement for two Federal tests (Section 211.2.12-1(c)) as unreasonable and unnecessary.

Response:

The Agency is confident that the regulation can be complied with by all manufacturers. Shipment to the laboratory can be accomplished within the 24-hour time period. There are a number of shipping services which are capable of accomplishing rapid shipment of goods. Extensions can be granted on a case-by-case basis. However, extensions are not expected to be needed in the vast majority of CAT orders.

Subject to the exceptions discussed in the preamble to the General Provisions (40 CFR, Part 211 Subpart A, §211.1.10), EPA will absorb the cost of testing when EPA conducts tests under Section 211.1.11 of the General Provisions, Testing by the Administrator. The manufacturer only pays for LV, CAT or other tests that the manufacturer may be ordered to conduct. When EPA conducts the tests, the manufacturer pays for the shipment of products to EPA for testing by EPA.

6.3 Reporting Requirements

Several industry representatives raised objections to the reporting requirements in the proposed rules. Bilsom (1 and 44), the Industrial Safety Equipment Association (ISEA) (38) and E-A-R Corporation (40) contended that Section 211.2.9-(4)(b) should be stricken since the production volume information required is confidential, proprietary, and irrelevant to the purposes of the rules. Bilsom International also indicated that the information called for falls outside EPA's statutory authority for the program. ISEA (38) believed that the enforcement provision greatly magnified the requirements of the manufacturers as stated in Section 13 of the Noise Control Act.

Response:

The U.S. Court of Appeals of the District of Columbia in the case of Atlas Copco., Inc., et al. vs. Environmental Protection Agency ruled on April 27, 1978 on a production schedule information request made by EPA to the portable air compressor industry. The court indicated that the Agency is entitled to request a reasonable amount of information concerning production scheduling and ordered the Agency to keep such information confidential. The Agency believes that the rationale of this ruling carries over to other product areas.

The Agency believes that reporting requirements are reasonable and necessary to assure compliance with the regulation since manufacturers control label verification testing and will do most of any Compliance Audit Testing.

6.2.3 Compliance with Label Values

An official of NIOSH (51) suggested alteration of the procedural requirements for compliance of verification testing with labeled information. The major complaint was that the manufacturer is "not given a statistically rational basis for labeling his devices." He is required to present mean attenuation values that will never be higher than the results of future compliance audit tests. NIOSH feels that a better approach is to require the manufacturer always to provide the exact attenuation and standard deviation from tests used in the calculation of the NRR. Then a hearing protection device will be considered out of compliance if the attenuation values arrived at through compliance test procedures are significantly less than the labeled mean attenuation values at the respective frequencies. A method of determining significance was suggested by NIOSH. ISEA (38) recommended that EPA develop a data base for determining the appropriate statistical test for compliance, and suggested procedures for consideration in developing such a data base.

Response:

In response to these and similar comments, the Agency has included a 3 dB variability factor that will be used in comparing the mean attenuation values at the one-third octave bands as stated in the supporting information supplied with each protector, with those determined from Compliance Audit Testing (CAT). We will take enforcement action only in those cases where the CAT values are lower than the labeled one-third octave band values minus the 3 dB variability factor. For example, if at one of the one-third octave bands, the attenuation value is 20 dB, we will take action only when the CAT test result shows that the attenuation value at that one-third octave band is less than 17 dB (20 dB minus 3 dB).

6.4 Remedial Orders and Product Recall

The provisions for remedial orders and product recall attracted considerable attention from commenters. Two of these offered suggestions for an expanded program. The French Laboratory (18) recommended that hearing protectors which fail to meet the label performance standards be removed from the market, and the Forging Industry Association (26) urged EPA to prohibit all advertising and marketing claims not substantiated through the testing program.

Most commenters, however, were negative about these provisions, believing them to be too burdensome on manufacturers. One industry spokesman (37) felt that the Agency lacked the authority under the Noise Control Act to order a product recall, regardless of how serious the violation. Also objecting to the product recall remedy, the E-A-R Corporation (40) suggested that in the event of non-compliance, the manufacturer be required only to label the offending products within a reasonable period of time. A similar position was taken by ISEA (38), which argued that relabeling should only be required on devices manufactured after Compliance Audit Testing. Finally, ISEA, seeking clarification of many of the enforcement provisions, requested the Agency to specify the situations that would result in a product recall order.

Another manufacturer (60) proposed revisions in the rules circumscribing EPA cessation of production orders by vesting such authority only in the Administrator, and then only in writing with a copy sent to the manufacturer by registered mail.

Plasmed, Inc. (31 and 106) pointed out that remedial orders under Section 11(d)(1) of the Noise Control Act of 1972 would result in substantial costs to the manufacturer, which would be passed on to the consumer, and also noted that the court costs incurred in contesting an EPA remedial order would impose a heavy burden on a small company.

Response:

Protectors will be recalled in the event of a relabeling order, and will involve those products reasonably available to the manufacturer for relabeling. Recall will not entail tracing a product to the ultimate purchaser or user as is done with some medical supplies.

Traceability to the ultimate purchaser or user is not required in this rule. However, the Agency maintains the position that it is reasonable to require relabeling of protectors in a manufacturer's possession or in the distribution chain, or to take other steps to remedy non-compliance. The reasonableness of a remedy, of course, will depend on the facts of the particular case. The manufacturer subject to a remedial action has the right to a hearing under section 11(d)(2) of the Act. At the hearing, held according to 5 USC Section 554, the manufacturer can challenge both the existence of the violation and the appropriateness of the remedy.

6.5 Effective Date of Regulation

The time period between the date of promulgation of the Final Rule and the effective date of the regulation drew a considerable number of comments, most of which urged an extension of the six-month time limit.

The Industrial Safety Equipment Association (ISEA) (38) cited five reasons why it felt the proposed six-month effective date should be extended to an 18- to 24-month period: (1) low number of adequate test facilities; (2) time requirement for testing; (3) required packaging, art work and tooling changes; (4) long lead times for plastic packaging; and (5) the need to deplete inventories of non-complying items.

Other manufacturers (44, 52) suggested that the implementation period be extended to at least 12 months. E-A-R (52) noted that the additional costs for a six-month period, as opposed to a 12- to 18-month period, would be "substantially greater than $50,000", consisting mainly of repackaging, scrapping or modifying current inventory, conversion to new packaging, and lost sales. Flents Products (60 and 101) suggested that sufficient implementation lead time be provided to allow for importation and manufacturing difficulties; a Flents representative noted that containers and other packaging materials are often ordered 15 months ahead of time.

Response:

The Agency, after carefully considering the industry's comments, has decided that the effective date of the regulation should be extended to one year after the date of promulgation of the Final Rule. This change is incorporated into the regulation in Section 211.2.2. Many of industry's other concerns relating to the effective date of the regulation, such as the time needed for packaging changes, are essentially eliminated through the Agency's modified approach to labeling requirements for bulk protector sales to industry, discussed in Section 4 of this Docket Analysis.

SECTION 7: ECONOMIC EFFECT

7.1 Costs of Testing

The majority of submissions to the public docket dealing with the economic effect of the labeling regulation focused on industry concerns. The Industrial Safety Equipment Association (ISEA) (38) contended that the proposed regulations, contrary to the Preamble of Subpart A, were economically detrimental to the industry. Flents Products (104) and Plasmed (31) expressed the opinion that the proposed rules could pose impossible economic burdens on smaller companies. Similarly, several firms (44, 101, 106, 33) felt that the regulations would place an unfair economic burden on producers of insert protectors, making them less competitive with producers of muff protectors.

There appeared to be agreement, on the part of the protector industry, that EPA underestimated the cost to the industry of implementing the regulatory requirements (28, 40, 44, 106). E-A-R Corporation stated that their estimates for implementation total nearly one-fourth of that which EPA estimates for the entire industry (40). Many comments addressed the issue of testing costs. The ISEA (38) suggested that label verification testing alone could nearly consume the EPA estimate of $400,000 to $500,000.

Wilson Products, Flents Products, and Plasmed (103, 60, 101, 106) each estimated a testing cost approaching $2,000 per product. Comments by Plasmed and Wilson Products (106, 103) raised the problem that each size of insert, and each ear muff configuration might require its own test, resulting in significant costs per design. Plasmed (38) estimated that testing alone would contribute an 8/10 of a cent increase per unit.

Response:

As was stated earlier in the economic analysis (Section II, Part I of this analysis), the Agency has revised upward its original economic analysis based, in part, on industry's cost estimates and the Agency's additional research.

In the Draft Background Document for the Labeling of Hearing Protectors, April, 1977 [4] the cost to the industry was based on the previously determined size of the industry to be 40 manufacturers. The economic information presented in this revised analysis is based on having determined the industry to be 70 manufacturers and distributors.

However, distributors in this industry are not likely to incur the costs of complying with these requirements to the same extent that manufacturers will. They generally repackage protectors supplied by manufacturers, and put their brand names on the packaging. Therefore, a single device may be marketed under several different private labels.

With this aspect of the industry in mind, the regulation states that distributors may use a manufacturer's previously developed Noise Reduction Rating and Mean Attenuation data when packaging and labeling protectors. Therefore, in these situations, the only costs incurred for complying with the requirements of this regulation would be the labeling costs as a result of repackaging, not the testing, and recordkeeping.

The Agency based its estimates of first-year testing costs on the testing of all models of protectors in each of their use-positions (as many as three positions for muff-type protectors) - these costs are not expected to exceed $350,000. The Agency's best estimate of first year testing costs range from $262,500 (175 model configurations x $1500 per test) to $350,000 (175 x $2000 per test).

The annual cost estimate of this regulation for testing is based on including: costs for Compliance Audit Testing by not more than 15% of the industry in one year (approximately $21,000); and label-verifying of new classes of protectors or classes of protectors that in one year have undergone changes which result in decreased noise reducing effectiveness (this is not expected to exceed 10% of the models of protectors in one year with a resultant cost of approximately $35,000).

7.2 Administrative Costs

Charles Machine Works, Inc. (37) noted difficulty in understanding Section 211.2.12-7(a), which appeared to be a costly testing process. Bilsom International (44) pointed out a conflict between the section in the General Provisions on Testing by the Administrator and the section in the Hearing Protector provisions on Compliance Audit Testing, and suggested that EPA bear the cost of this testing. Plasmed (31) suggested that EPA develop a less costly objective test.

Several industry spokesmen (31, 38, 106, 44) mentioned additional administrative costs required for implementation. These included costs for such things as clinical, legal, and managerial support. Plasmed (30) estimated an additional 4/10 of a cent increase per unit for clerical and legal support (31).

Response:

Section 211.2.12-7(a) applies to additional testing required only if a protector is found to not comply with its label as a result of Compliance Audit Testing. This cost will not be incurred for protectors that comply with their labels.

In response to the perceived conflict between the General Provisions and the Hearing Protector regulations with respect to who will bear the costs of testing, there is no conflict.

Section 211.1.11 of the General Provisions, Testing by the Administrator, reserves to the Agency the ability to test products as a part of its enforcement strategy. The manufacturer submits products to EPA upon request, and EPA conducts the test. The Administrator may test at any facility and will use Agency equipment. This will assure the Agency that testing is being conducted properly. The cost of testing under this section is borne by the Agency. The cost of shipment is borne by the manufacturer.

Section 211.2.12 of this regulation, Compliance Audit Testing, details a specific procedure which the Agency will use to assure itself that manufacturers are continuing to produce complying products after the label verification test. This section is designed to minimize the number of tests that a manufacturer will have to perform while still providing assurance to EPA that only complying products are being distributed in commerce. The manufacturer bears the cost of Compliance Audit Testing.

In short, subject to the exceptions discussed in the preamble to the General Provisions, EPA will absorb the cost of testing when EPA conducts tests under Testing by the Administration. The manufacturer pays for Label Verification, Compliance Audit Testing, or other ordered tests. The manufacturer pays for the shipment of products for testing, including shipment of products to EPA where EPA conducts the test.

As for additional administrative costs required for implementation of these requirements, the Agency considered these costs in detail (see Section II, Part I of this analysis for details).

7.3 Label Size Requirements: Cost

Factors associated with the actual labeling operation were mentioned by many commenters. Such things as label design (38), label printing (38), materials (61), loss of existing inventory that has been made obsolete (38, 40), and labor for attaching labels (38) were given as specific factors contributing to increased costs. Industry representatives (31, 106, 102) suggested that, for monetary reasons, pasting labels is preferable to embossing or labeling done in the process of molding protectors.

Many industry representatives (38, 40, 106, 44, 103, 60, 36) suggested that the label size requirements would dictate packaging changes. Specific aspects of the packaging process mentioned by the commentators as affecting costs include tooling costs for manufacturing new containers (38), modifications to or replacement of containers (38), increased shipping costs (38, 40), obsolete inventories (44), and storage costs (44). Wilson Products (103) indicated that the cost of packaging could exceed the cost of the product. Flents Products (36, 60) estimated that labeling might add 83 percent to container costs.

Other commenters (38, 101) addressed the costs of designing and printing supplemental information sheets or inserts. Other specified costs included training of sales force and distributors (38) and revisions to promotional literature (38). Bilsom International (44) emphasized that the additional costs associated with satisfying nation-by-nation labeling requirements were also being neglected.

Response:

The Agency considered the costs associated with the actual labeling operation and revisions to promotional literature in Section II of Part I of this document.

With respect to label size requirements and the costs associated with changes in packaging, the Agency is requiring the labeling of protectors according to the method by which they are displayed at the point of sale to the ultimate purchaser or distribution to the prospective user (see Section 4.3 of this Docket Analysis for further explanation). Therefore, any costs that would have been attributable directly to changes in packaging to accommodate a label have been essentially eliminated.

Costs associated with the compliance of products exported to other countries and subject to their regulations are the responsibility of the company engaging in that international commerce.

7.4 Effective Date and Associated Costs

Time factors associated with the regulation were mentioned as having an influence on cost. Bilsom International (1) suggested that advance approval of labels could be a source of costly delay. E-A-R Corporation (52) estimated that the additional costs for a 6-month period as opposed to a 12- or 18-month period of compliance could be substantially greater than $50,000. Factors contributing to this were: purchases of supplies in small amounts; scrapping or modifying present inventory, lost sales; and covering down-time with sufficient inventory.

Plasmed (31) estimated that the overall cost for meeting the regulations would be three cents per unit. Aural Technology (61) also estimated a few cents per unit, and suggested that this was reasonable for a unit otherwise costing $5.00. Plasmed (106) asserted that the manufacturing costs to producers selling in bulk to other firms would more than double. Flents Products indicated that the cost of package inserts, depending upon the information required, would be under three cents a piece (101).

Comments by certain manufacturers (44, 36) indicated concern that the proposed regulations would have serious economic impact on the industry without a corresponding benefit to the consumer. Mott Corporation (23) expressed opposition to the labeling program because of, among other things, the higher cost to both taxpayers and consumers. The Department of Labor of North Carolina suggested that the cost of the regulations might increase price beyond the public's willingness to pay, and warned about the possible decrease in use of hearing protectors because of cost. Finally, the Industrial Safety Equipment Association (38) suggested that the costs might deter development of new or improved protectors by both old and potential manufacturers.

Response:

The modification of Section 211.2.2 extends the effective date to one year after promulgation of the Final Rule. This change is intended to allow manufacturers to minimize the obsolescence of packaging and literature supplies that they may have on-hand due to the lead-time procurements necessary in this industry. The extension provides a longer phase-in period for the testing requirements, and also allows extra time for greater availability of testing laboratories, thereby reducing a potential supply/demand imbalance that might cause an increase in test cost.

Advance approval of labels is not required in this regulation, so it will not "be a source of costly delay".

It is the practice of the industry to pass 100% of production costs through to the ultimate purchaser. We believe this practice will continue.

While the potential percent price increase per pair of protectors is impossible to determine in the absence of market size information, the Agency estimates, based on limited data, that prices may increase between $0.03 and

$0.05 per pair of insert devices (if previously bulk-packaged protectors are required to be individually packaged and labeled), and $0.10 for "muff" devices.

These final hearing protector labeling requirements reflect the Agency's overall sensitivity to the costs that accompany regulation, and our policy, with respect to product labeling, of minimizing the economic impact of a regulation. The Agency is requiring that labeling of protectors be done in a method compatible with current marketing practices, which reduces the probability of packaging changes and associated cost increases.

The Agency has had no indication that this rulemaking would impose appreciable burdens on any manufacturer within the hearing protector industry, nor that the regulation in itself will result in business closure. Also, our economic analysis did not attempt to predict potential market shifts or potential adverse economic effects that might occur as a result of labeling requirements which would identify some protective devices as being low in effectiveness. The Agency believes that any market shifts or other economic effects beyond the direct costs of labeling are solely related to the competitive nature of this industry. We believe that the industry will adjust itself to reflect purchasers' and users' selections made as the result of newly available information from these noise labeling requirements; not as a result of the restrictions of command and control regulations.

REFERENCES FOR PART II

1. Federal Register, Vol. 42, June 22, 1977, p. 31730.
2. Federal Register, Vol. 42, June 22, 1977, p. 31722.
3. Regulatory Analysis Supporting the General Provisions for Product Noise Labeling, EPA 550/9-79-255, August 1979.

CONSULTANTS AND EXPERTS

Department of Defense, Robins Air Force Base, GA

National Institute for Occupational Safety and Health (Department of Health, Education and Welfare)

Mine Safety and Health Administration (Department of Labor) (Formerly Mining Enforcement and Safety Administration)

Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, OH

Civil Aeromedical Institute (Federal Aviation Administration - DOT)

Environmental Acoustics Laboratory, Pennsylvania State University

APPENDIX A

DEFINITION OF ISSUES FROM EACH DOCKET ENTRY

HEARING PROTECTOR DOCKET 77-5:

Docket Number, Name, Affiliation	Comments
77-5-001 Roland Westerdal President Bilsom International, Inc. (letter dated 5/10/77)	1. Suggested that the inclusion of required information in sales literature would be a more effective means of reaching the persons who make the purchase decisions in industrial settings. 2. Recommended that consideration be given to the development of standards that reflect the factor of wearability. 3. Maintained that a rating scheme which defines classes of hearing protectors offers no advantage to either the consumer or the manufacturer and should not be adopted. 4. Pointed out the limitations of objective testing. 5. Suggested that the Administrator's analysis of costs should reflect the additional costs associated with satisfying nation-by-nation requirements. 6. Pointed out that, due to variability in test results, manufacturers could not guarantee even a very conservative NRR value. 7. Indicated that since the end user is not necessarily the buyer, reporting the NRR and supporting information to the end user would not serve the stated purposes of the program. 8. Suggested that the information provided to the end user emphasize proper use instructions. 9. Requested that the regulation be flexible in its labeling requirements to reflect reasonable realities of marketing and manufacturing. 10. Requested clarification as to the unit which "must be labeled to include this information and to contain enclosures with supporting information." 11. Asked that the regulations consider the impact of aging in evaluating a device's effectiveness. 12. Pointed out that production volume information cannot be requested pursuant to the authority vested in the Administrator by the Act.

Docket Number, Name, Affiliation	Comments
77-5-001 (continued)	13. Requested the opportunity to examine and comment on regulations concerning imported hearing protective devices.
	14. As a means of not discouraging product innovation, requested that regulations not be applicable to new products for a period of 12 months after their entry into the market.
	15. Suggested that the advance approval of labels could become a source of costly delay in the distribution of devices, and indicated that the annual verification requirement is unnecessary.
	16. Enclosed:
	a. Bilsom International study regarding the relationship between wearing time and effect of personal hearing protectors.
	b. Dennis Else, The University of Aston in Birmingham, Great Britain, "A Note on the Protection Afforded by Hearing Protectors-Implications of the Energy Principle."
	c. Bilsom suggested resale price lists showing minimum quantities offered for sale to end users.
-002 Marlene K. Olinger Administrative Assistant Bilsom International, Inc.	1. Resubmitted Bilsom's letter of 5/10/77 (77-5-001), reordering the enclosures and placing them on Bilsom paper, but including no new information.
-003 Thomas A. Scanlon President Tasco Corporation	1. Requested clarification on the question of whether compliance testing would be done by a government agency or each manufacturer.
	2. Noted that ASA STD-1-1975 calls for a band force report but fails to specify how a hardhat hearing protector attachment is to be measured for force.
-004 Stuart M. Low President Flents Products Company	1. Wrote to confirm a phone call to EPA to clarify certain points in the proposal rather than to submit a formal response.

Docket Number, Name, Affiliation	Comments
77-5-004 (continued)	2. Noted that the EPA official informally stated that printing in the specified manner on the packaging could satisfy the labeling requirement.
	3. Noted that the EPA official informally stated that information printed on "hang cards" would not be acceptable, and that each small earplug container would have to display the labeled information.
	4. Asked confirmation of his understanding of the above responses.
-005 Elizabeth Platt	1. Suggested that the scaling system used in the program be explained.
	2. Noted that the consumer should be informed if the scale used is linear, logarithmic, or otherwise, to assure that the labels be properly understood by the intended audience.
-006 Phillis H. Rosenthal	1. Though referred to this docket, comment called for abatement of detrimental lawnmower and grass and leaf blower noise.
-007 Thomas J. Woods Aural Technology, Inc.	1. Expressed thanks to EPA for information on the program provided to ATI.
	2. Enclosed literature on the firm's "Protectear" product, and noted that it should be tested only by Jack Vernon's attenuation method and not by ANSI 3.19-1974.
	3. Enclosed a typical letter sent in response to inquiries about the firm's product, which describes the features of "Protectear."
	4. Enclosed vita of Jack Vernon and a note of his comments on ASA-STD-1-1975.
-008 (omitted)	

Docket Number, Name, Affiliation	Comments
77-5-009 Paul L. Michael, Ph.D. Professor of Environmental Acoustics Pennsylvania State University	1. Noted that NIOSH does not use the single-number designation "NRR." 2. Warned that "NRR" might be construed as "Noise Regulation Reporter" and suggested "SLD" (Sound Level Difference) be used instead. 3. Pointed out that many Federal agencies (e.g., DOL) use the term "sound" rather than "noise." 4. Noted, re: page 31731, Col.1, Para. 2, Line 1-5, that the "A" weighting does not approximate the threshold of hearing, and that "C" weighting is relatively unweighted only at the center frequencies. 5. Expressed the opinion that the procedure for a single-number rating method is needlessly complex, suggesting a simpler approach expounded in his paper for DOL (attached). Also suggested citation of the long method of calculation as discussed in the attachment. ("OSHA Methods for Determining the Effectiveness of Ear Protector Devices.") 6. Noted that the minimum label size may have a significant economic impact on the manufacturers of insert-type hearing protectors. 7. Re: page 31733, Col. 1, Para. 1, Line 7-12, suggested that for consistency, the means minus two standard deviations rather than just the mean attenuations be compared. 8. At 211.2.3(b) and (c), suggested changing ANSI Z22.540-1957 to read ANSI Z24.22-1957. 9. Proposed a standard definition for impulsive sound. 10. Noted that re: page 31734, Col. 1, Para. m, the NRR symbol is not used in NIOSH Publication No. 76-120 and, at Para. n, the heading should read "one-third octave band." 11. Expressed support for an NRR rating for each wearing position.

Docket Number, Name, Affiliation	Comments
77-5-009 (continued)	12. Mentioned that it would not be feasible to randomly select ten test subjects who would require all protector sizes. Suggested wording should be changed to "all sizes must be available in conducting the required test." 13. Noted the heavy economic and testing burden of the requirement for once-a-year testing.
-010 R.A. Smith	1. Expressed strong support for EPA's hearing protector labeling proposal.
-011 David Rankin	1. Urged EPA to move ahead with the program, pointing out that it would pressure companies into the competitive market.
-012 Kenneth R. Freitas	1. The respondent, an employee with the United States Postal Service, described the noisy environment in which he worked. 2. Reported that he had written a letter of complaint to his supervisor but that he had not received a reply. 3. Questioned whether the United States Postal Service was subject to the standards and regulations administered by the EPA. 4. Asked what recourse he had to protect his personal interest. 5. Asked what EPA could do to his employer to rectify the situation. 6. Asked whether an on-site investigation of the situation could be made.
-013 Jane A. Baran, Director Audiology/Aural Rehabilitation Indianapolis Speech and Hearing Center	1. Expressed support of labeling regulations for hearing protectors on behalf of audiological staff at the Center, citing noise pollution as a prominent problem in society. 2. Asked to be kept informed of any further developments in this area.

Docket Number, Name, Affiliation	Comments
77-5-014 H.E. Douglas, President H.E. Douglas Engineering Sales Co.	1. Wholeheartedly endorsed the proposed ruling. 2. Suggested that the label should state the noise reducing capability at the following nominal frequencies: .125; .25; .5; 1; 2; 3.15; 4; 6.3; 8. 3. Felt that 0 to 31 did not mean much since there are very few manufacturers, if any, that have a reduction in the low figures below 125. 4. Pointed out that there are also very few devices that show a 31 on any of the first four figures. 5. Suggested that labeling should be in the 500 to 3,000 range, which is the area most critical for protection of one's ears in the speech field. 6. Pointed out that very few people who have been exposed to noise are able to hear efficiently in the high frequencies. 7. Pointed out that as long as protection is used in the 3,000 Hertz and lower range, noise doesn't interfere with speech conversation.
-015 Margaret R.A. Paradis Leboeuf, Lamb, Leihy & MacRae (Attorneys)	1. Requested, pursuant to the Freedom of Information Act, the data received by EPA in response to a request made of nine hearing protector manufacturers, referred to on page 38 of the Background Document, with proprietary information masked. 2. Attached a copy of the first page of a letter of request from EPA to one of the nine aforementioned firms, Mine Safety Appliances Company.
-016 Robert G. Palaso, for Donald P. Schlick, Ass't. Administrator, Technical Support Mining Enforcement and Safety Administration (MESA) U.S. Department of the Interior	1. Expressed agreement with EPA's intent and action in the program. 2. Noted that the inclusion of two standard deviations actually applies 95% confidence levels to the attenuation values, while the 98% figure refers to NIOSH 3dB adjustment factor. 3. Pointed out that the use of NIOSH Method 2 will be a confusing factor by requiring measurement in "C" weighted decibels.

Docket Number, Name, Affiliation	Comments
77-5-016 (continued)	4. Noted MESA's revision of regulations to allow use of the dosimeter in measuring worker noise exposure and stated its preference for a method reliant on "A" weighted decibels (dB(A)) alone. 5. Since many Type 2S sound level meters are in use in industry, he pointed out that requiring Method 2 with its C-weighting would render such devices obsolete. 6. Suggested a permanent NRR on the device itself, an especially important feature for MESA enforcement officers. 7. Expressed a preference for an exclusively dBA-based method with a conservative underestimation of the R factor rating for the sake of simplicity.
-017 Stuart M. Low Flents Products Company, Inc. (dated 8/23/77)	1. Expressed no quarrel with Public Law 92-574, the Noise Control Act of 1972, nor with the intent of the proposed rules. 2. Suggested that allowing comments to be made in writing was not a satisfactory substitute for a public hearing. 3. Suggested that the future of his business would be seriously affected if the proposed regulations were put into effect. 4. Strongly urged the holding of public hearings.
-018 Hugh Crozier French Laboratory	1. Stated that an agency of the Government should be set up for testing all attenuators. 2. Pointed out that the agency doing the testing should not have a conflict of interest where they are attempting to develop a device of their own such as the V51R. 3. Suggested that tests be conducted for attenuation, comfort, wearability, personal hygiene, acceptance, required maintenance, length of time for wearing comfort, length of time the product remains as initially tested, and whether the product remains in place during various mouth maneuvers.

Docket Number, Name, Affiliation	Comments
77-5-018 (continued)	4. Suggested that the only true guarantee is to test the product on the individual who is to wear it. 5. Suggested that test results obtained from best fit subjects and subjects whose test results vary too much should not be used for any publication, advertising, or labeling. 6. Suggested that test results obtained from best fit subjects and subjects whose test results vary too much should be used solely to determine the percent of people that may be able to use such a protector. 7. Suggested that a true test would select subjects at random and use all test results, and that the reporting of test results without including all subjects should be considered fraudulent. 8. Suggested tests of protector material to determine how readily it would accept bacteria and foreign objects and to determine its potential irritation to users under normal use. 9. Pointed out that the seal on muffs depends on the skin and hair contact made, the actual head and bone structure, and the stiffness of the seal. 10. Pointed out that most seals begin to stiffen in three to four months and should be replaced at that time. 11. Took exception to the inference that custom fitted protectors may not be used in ears that have problems and pointed out that they have made ear protectors for many post-operative ear cases. 12. Suggested that ear protectors not meeting required standards should be removed from the market place.
-019 Frank E. Wilcher Executive Director Industrial Safety Equipment Association	1. Requested an extension of the period for comment on Subpart B to coincide with that of Subpart A (that is, October 28, 1977). 2. Requested a public hearing on the hearing protector provisions.

Docket Number, Name, Affiliation	Comments
77-5-020 David Fishken, Ph.D. Department of Psychology Northeastern University	1. Expressed interest in acquiring all available information on the proposed noise labeling program, specifically requesting information pertaining to hearing protector labeling. 2. Stated that his interests concerned the methods used to establish label values, test methodologies, and the role that private industry can play in promoting the program.
-021 Singapore Institute of Standards and Industrial Research	1. Requested a copy of the proposed regulations on hearing protector labeling and asked to be informed of future developments.
-022 Rudolf Donninger Osterreichisches Normungsinstitut (Standards Institute for Government of Austria)	1. Noted the intention of the Austrian government to propose hearing protector labeling requirements and requested reasons why EPA did not choose International Standard 4869 as the measurement of sound attenuation. 2. Included draft of Internatinal Standard 4869. a. Test signals consist of white noise filtered through one-third octave bands with ten center frequencies reported. b. Ten listeners are used per test, with statistical results reported for each subject.
-023 E.S. Mott Mott Corporation	1. Expressed opposition to the labeling program because of excessive Federal regulations, higher costs for consumers and taxpayers, and the ability of the public to make wise purchasing decisions in the absence of noise labels. 2. Suggested that bureaucrats be required to have five years of practical experience in private industry.
-024 John T. Hughes State Lobster Hatchery and Research Station (Mass.)	1. Expressed approval of proposed actions taken by EPA under authority of Section 8 of the Noise Control Act.

Docket Number, Name, Affiliation	Comments
77-5-024 (continued)	2. Suggested that public education material be distributed which describes dBA's, their measurement, and the required equipment.
-025 Katherine M. Reilly Audiologist Marin General Hospital	1. Requested current and future information on labeling standards and requirements for hearing protectors.
-026 Michael N. Winn Director of Industrial Relations and Government Affairs Forging Industry Association	1. Gave background information on Forging Industry Association. 2. Pointed out that not quite half of the 89,000 persons employed in the forging industry were exposed to noise levels above 90 dBA. 3. Supported efforts to standardize the testing and performance claims of devices marketed as hearing protection equipment since this equipment is essential to the Forging Industry. 4. Stated preference for voluntary compliance by all manufacturers. 5. Suggested that the labeling requirements apply to all products marketed in interstate commerce as personal hearing protection devices including plugs, muffs, Swedish wool, etc. 6. Suggested that the regulation should require that a manufacturer provide separate testing for devices which may be worn in a variety of ways. 7. Suggested that EPA should prohibit all advertising or marketing claims not substantiated by the required testing program. 8. Suggested that EPA should require that testing results as certified by EPA be provided by the manufacturer upon request from a customer or potential customer. 9. Urged that the regulations include a rating system which states the attenuation factor for each frequency, and that the labeling system make provisions for reporting attenuation factors at each individual frequency.

Docket Number, Name, Affiliation	Comments
77-5-027 Frederick G. Crocker, Jr. Vice President and General Manager Safety Products Division Norton Company	1. Asserted that two of Norton's products-SONIC EAR VALVS and the SONIC II protectors-cannot be tested using ASA STD 1-1975/ANSI STD S3.19-1974 and thus cannot be assigned an NRR number. Norton therefore expects to file for an exception to certain Subpart B regulations under the procedures outline in Sec. 211.2.5. 2. Approved of Sec. 211.2.5 in principle, subject to the following comments: a. "Second sentence of Sec. 211.2.5(a) should be limited to apply only to devices not already on the market as of the effective date (or the date of promulgation) on the final regulation." b. Alternative procedures should be established for devices already on the market, as it is unfair to force discontinuance of an effective product simply because there has not been the time (nor opportunity) to submit an application containing a "suitable alternative rating system" supported by "conclusive scientific test data." A period of at least a year after the effective date of the rules should be allowed to prepare the application. c. "Suitable" is not defined in phrase "suitable alternative effectiveness rating." Submitted that a "suitable" alternative rating system for a device for which NRR is not an accurate indicator can be independent and unrelated to NRR system. d. Sec. 211.2.5(c) does not define what constitutes "conclusive scientific test data" (suggests language). 3. Changes proposed are designed to permit continued marketing during testing and processing of application. 4. Noted that other views of the Norton Company will be reflected in the comments of the Industrial Safety Equipment Association.

Docket Number, Name, Affiliation	Comments
77-5-028 H.J. Wise W.H. Brady Co.	1. As a manufacturer of nameplate and labeling products, Mr. Wise expressed interest in reviewing all proposed labeling regulations and requested a copy of those pertaining to hearing protectors.
-029 David M. Anderson, Ph.D. Manager, Environmental Quality Control Bethlehem Steel Corporation	1. Suggested that information be required on the label or in the supporting information about how the NRR should be used to determine the A-weighted level at the eardrum.
-030 Jerry V. Tobias, Ph.D. Civil Aeromedical Institute U.S. Federal Aviation Administration	1. Respondent found the proposals sensible and responsible, particularly commending use of the attenuation value minus two standard deviations. 2. Objected to the use of the decibel number (rather than the rating number in product classes) as not in the public interest because of: a. Arbitrary rounding and measurement error. b. The greater benefit to consumers of classification numbers. c. The precedent for agricultural product classification by the Federal government (e.g., eggs, butter and meat). d. The ease of product comparison that such a classification allows. e. The likelihood that most hearing protectors would rank in the higher classes while a decibel rating could hurt good products in marginal cases. 3. Submitted (a) paper presented by the respondent to the International Congress on Acoustics which sets forth an approach to hearing protector classification, and (b) two other selected papers, entitled (1) The Typical Noise: First step in the Development of a Short Procedure for Estimating Performance of Hearing Protectors (Jerry V. Tobias and Daniel L. Johnson).

Docket Number, Name, Affiliation	Comments
77-5-030 (continued)	(2) Earplug Rankings Based on the Protector-Attenuation Rating (P-AR). (Jerry V. Tobias) 4. Respondent's ILA paper, "Statistically Based Rating System for Hearing Protectors" stated that hearing protector effectiveness is determined by the statistical distributions of: a. The noise spectra in which the device is used. b. The variability of attenuation characteristics of each device for a variety of potential users in a given noise environment. c. The attenuation variability for a variety of hearing protectors used by a given population in a given noise environment. 5. The paper noted that hypothetical noises must be developed for a valuable average rating. 6. The paper pointed out the value of the "mean minus one or two standard deviations" approach. 7. The paper proposed a Protector-Attenuation Rating (P-AR) derived from previously calculated attenuations for many types of protectors. Those protectors scoring at least two standard deviations above the mean form Class 1; one standard deviation above, Class 2; those at the mean, Class 3; and so on to Classes 4, 5, and 6. The P-AR takes account of all three factors determining protector effectiveness.
-031 John M. Ruffner President Plasmed, Inc.	1. Expressed concern over meeting Plasmed's labeling responsibility as an original ear-plug manufacturer, through the complexities of the distribution process. 2. Inquired if test would have to be conducted separately for each customer, which would result in prohibitive testing costs for the firm. 3. Noted that the proposed rules conflict with Armed Forces' requirements for packaging. 4. Pointed out that the firm has never sold a pair of earplugs to an individual customer, specializing instead in bulk sales.

Docket Number, Name, Affiliation	Comments
77-5-031 (continued)	5. Inquired about EPA's intention for labeling of cotton given its use as a major competitor to earplugs in hearing protection.
	6. Ranked customer priorities for earplugs as comfort first, freedom to work second, and noise suppression third.
	7. Suggested that EPA develop an objective test at a lower cost than the proposed procedure.
	8. Pointed out that the rules would entail an estimated cost of 3 cents per unit, a substantial portion of the earplug's selling price. The figure consists of 8/10 cents for initial compliance testing, 4/10 cents for clerical and legal support, and 1-8/10 cents for actual labeling operations.
	9. Added that if mold changes were necessitated for labeling, an additional cost of approximately $100,000 for the firm's production line would result.
	10. Pointed out that the cost impact for ear muff manufacturers would be fractional compared to that for bulk earplug manufacturers.
	11. Noted that remedial order under Section 11(d)(1) of the Act would result in further substantial costs to be passed on to the customer.
	12. Pointed out that as a small firm with a net worth of less than $100,000, the proposed rules, aimed at the individual rather than bulk consumer, could pose impossible economic burdens.
-032 Lawrence H. Hodges Vice President, Technical Affairs J.I. Case Company	1. Explained the manufacturing scope of the J.I. Case Company.
	2. Explained that some of their employees used hearing protectors.
	3. Agreed, in principle, with the proposed regulations.

Docket Number, Name, Affiliation	Comments
77-5-032 (continued)	4. Recommended a reasonably permanent label as opposed to a label which remains intact only until the time of first retail sale. 5. As a first choice, recommended that the label be placed on the hearing protector and, as a second choice, on the carrying case. 6. Felt that the continuing availability of attenuation data would allow future comparisons with improved protectors to determine whether replacement was cost-justified for the protection of employees.
-033 Thomas J. Woods President Aural Technology, Inc.	1. Submitted a request for an exception to test procedures (for a vented device).
-034 L. A. Weaver Department of Labor Acting OSHA Director State of North Carolina	1. Expressed doubts about the individual consumer's ability to properly use the NRR to make product comparisons, although industrial users would benefit from the NRR. 2. Noted that the costs of the regulations might increase the price of hearing protectors beyond the public's willingness to pay. 3. Noted the need for proper consumer education and fit of the protector. 4. Expressed a preference for performance regulations rather than the testing specification standards in the proposed regulations. 5. Suggested that EPA, and not the manufacturers, bear the cost burden for testing. 6. Warned about the possibility of decreased use of protectors because of increased costs under the regulations, and urged EPA to provide product testing as a service rather than requiring it as a regulation.

Docket Number, Name, Affiliation	Comments
77-5-035 Edwin W. Abbott, Manager Operational Facility Requirements Air Transport Association of America	1. Stated that the Air Transport Association has no additional information to offer regarding the effectiveness rating, or facilitation of the enforcement of the labeling requirements for hearing protectors, as requested by the Environmental Protection Agency.
-036 Stuart M. Low, President Flents Products Company, Inc.	1. Gave some company background and pointed out that approximately 95 percent of their sales are in anti-noise devices.
	2. Pointed out that many of the proposed noise labeling requirements were impractical, would raise costs substantially, and would provide only limited benefit to the potential user of hearing protectors.
	3. Pointed out that the required 1-1/2" x 2" primary label would not fit any of the containers currently marketed by their company and would require containers two or three sizes larger than those currently used.
	4. Elaborated on the issue of container size and pointed out that the cost increase of a container capable of accepting a 1-1/2" x 2" label for one item alone would amount to $10,000 a year, an 83 percent increase.
	5. Suggested that the Agency allow some flexibility in the dimensions of the required labeling.
	6. Pointed out that respirator labels required by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health have no minimum dimensions. Questioned the need for substantially more severe labeling requirements on hearing protectors, not used for protection in life endangering conditions, than those required for respirators.
	7. Strongly urged that the rules be redrafted to allow Noise Reduction Ratings and other information required by Section 211.2.4-1 to appear in a package insert for products sold at retail, as permitted under Section 8(b) which gives the Administrator considerable latitude in specifying the manner in which information is to be disseminated to the potential user.

Docket Number, Name, Affiliation	Comments
77-5-037 Gerald A. Stangl, Ph.D. Design Engineer The Charles Machine Works, Inc.	1. Noted marketing problems in requiring date of production on the label and suggested a production lot number or code instead. 2. Noted the size problem of the label for hearing protectors. 3. Pointed out difficulties in finding test subjects to test the full-size range of insert-type protectors. 4. Expressed difficulty in understanding Section 211.2.12-7(a), indicating a very costly testing process. 5. Suggested that finding one protector in violation of its noise attenuation value is an unreasonable basis for the application of penalties, arguing that noncompliance should be limited to serious jeopardizing of the public health and welfare. 6. Argued that EPA had no authority under the Act for a product recall, however gross the violation of the regulations. 7. Suggested that EPA adopt an "Acceptable Quality Level" for compliance audit testing and establish guidelines for the violations jeopardizing public health and welfare.
-038 Frank E. Wilcher, Jr. Executive Director Industrial Safety Equipment Association	1. Expressed fear that exclusive emphasis on the NRR would lead potential buyers to overlook factors of equal or greater importance such as comfort, cost, durability, and compatibility with other protective equipment. 2. Expressed concern over possible misinterpretation of the NRR and the comparative acoustic range. 3. Pointed out the existence of hearing protective devices for which an NRR may not represent the true protective quality of the device. 4. Suggested that physical measurement methods should not be applied to the evaluation of hearing protector performance until adequate procedures are developed.

Docket Number, Name, Affiliation

Comments

77-5-038 (continued)

5. Felt that EPA's estimates of the economic impact of the proposed rulemaking were grossly underestimated, both for initial testing and maintenance requirements.

6. Outlined in detail some of the elements which would increase manufacturing costs and suggested that many of these had been neglected by EPA.

7. Suggested that label verification testing alone would nearly consume the EPA estimate of $400,000 to $500,000. "NIOSH Document 76-120 lists 175 separate protector configurations which, at $2,000 per test, would cost $350,000; there are many protectors not listed in this publication."

8. Suggested that small manufacturers would bear an even larger relative burden when trying to cope with the significant fixed costs.

9. Felt that the costs and complexities of the proposed rulemaking would deter the development of new and improved hearing protectors by both existing companies and those wishing to enter the field.

10. Agreed with EPA that only production devices should be used for testing.

11. Suggested a phase-in period of 18 to 24 months since the proposed six-month effective date for the final rule is not adequate.

12. Reasons given for longer period were: (1) low number of adequate testing facilities; (2) time requirement for test; (3) required packaging, artwork and tooling changes; (4) long lead-times for plastic packaging; and (5) need to deplete inventories of non-complying items.

13. Suggested language which should be added to preclude concentration on the NRR as the only selection criterion for hearing protective devices. (Section 211.2.4-1, page 31734)

14. Pointed out that the existing range of NRRs was calculated under ANSI Z24.22-1957 and that the range under ANSI S3.19-1974 has not been computed. (Section 211.2.4-1(c), page 31734)

Docket Number, Name, Affiliation	Comments
77-5-038 (continued)	15. Suggested that EPA establish a theoretical "perfect" NRR for the upper limit of the range in order to avoid changes in the range values in the future.
	16. Suggested that ear muffs with multi-position headbands be labeled for each wearing position, to ensure the wearer does not underestimate the protective quality of the device due to his choice of wearing position.
	17. Suggested that EPA drop its mandatory label size requirement in favor of a requirement that the label be of sufficient size to be legible. The primary label size requirement of 1-1/2" x 2" will necessitate expensive packaging changes. (Section 211.2.4-2, page 31734)
	18. Suggested that EPA consider removal of redundant information, such as manufacturer's name and model number, from the label.
	19. Maintained that those making the selection decision would be better informed of a device's NRR through sales or technical literature. Therefore, Mr. Wilcher recommended the NRR be required on the master carton only, as opposed to the container of each device, since the purchase decision is more often made by someone other than the user in the industrial situation.
	20. Submitted that the proposed regulations are contrary to the Preamble of Subpart A in that the administrative, economic, ecological, and technical impacts of the program are substantially detrimental to the industry.
	21. Recommended that manufacturers be permitted to place the NRR on the display portion of consumer packages in a visible, legible manner "in a size and type of their own choosing."
	22. Recommended that EPA begin a large-scale educational program, before the rules go into effect, to give the public an understanding of the NRR and other facets of the Noise Control Act.

Docket Number, Name, Affiliation	Comments
77-5-038 (continued)	23. Suggested that lot control numbers would serve the same purpose as the month and year of manufacture and that the placement of this information should be left to the discretion of the manufacturer provided that it can be readily found. (Section 211.2.4-4(b), page 31734)
	24. Took exception to the statement recommending hearing protection against the harmful effects of impulsive noise and suggested new wording (Section 211.2.4-4(b), page 31734).
	25. Asked if EPA knew the number of laboratories presently equipped to perform testing in accordance with ANSI S3.19-1974, and if the Agency intended to publish a list of these laboratories.
	26. Strongly recommended that Section 211.2.9-4(b) (page 31735) be stricken since the information required is confidential, proprietary to the manufacturer, and irrelevant to the laboratory requirements proposed.
	27. Pointed out that the wording of Section 211.1.10-8 was unclear and could be construed to mean that the Administrator could require label verification testing on an annual basis for any product.
	28. Strongly disagreed with the methods for determining compliance since each company is able to determine what risk of non-compliance it wishes to incur, and then derate accordingly.
	29. Recommended that EPA develop a data base suitable for determining the appropriate statistical test for determining compliance and suggested a list of procedures for consideration in developing that data base.
	30. Suggested that EPA establish field testing procedures to be used prior to requiring a Compliance Audit Test and that probable cause be demonstrated prior to invoking this requirement. (Section 211.2.12-1(a), page 31737)
	31. Questioned the need for two tests given that ANSI S3.19-1974 was developed to provide meaningful data from one test. (Section 211.2.12-1(e), page 31737)

Docket Number, Name, Affiliation	Comments
77-5-038 (continued)	32. Suggested that EPA furnish manufacturers with a list of certified laboratories and that manufacturers have the opportunity to select the facility to perform the tests. (Section 211.2.12-1(c)(4), page 31737) 33. Suggested that the requirement for samples under Section 211.2.12-1(c)(5) should be consistent with usual practice for the type of device being tested. 34. Suggested a wording change in Section 211.2.12-1(e)(1) making it a requirement for the Administrator to extend the time requirement if the certified test facility is not available to conduct such testing. 35. Suggested a minimum 30-day requirement for completion of Compliance Audit Tests and automatic extensions if the laboratory is unable to meet the established deadlines. (Section 211.2.12-1(e)(2), page 31737) 36. Pointed out that a 24-hour requirement for shipping devices to a test facility was impossible to comply with and suggested that this be extended to at least one week. (Section 211.2.12-1(e)(3), page 31737) 37. Suggested that relabeling be required only on devices manufactured after Compliance Audit Testing. (Section 211.2.12-8, page 31738) 38. Requested clarification on a number of issues: Nos. 38-50. Questioned whether the proposed rulemaking would apply to both the industrial and consumer markets. 39. Questioned the manner in which EPA intended to regulate the labeling of devices sold unpackaged, in bulk quantities. 40. Questioned EPA's plans for developing an educational program to make purchasers aware of the NRR system. 41. Questioned whether the responsibility for label verification testing and Compliance Audit Testing was with the manufacturer of a device or the packager/distributor. 42. Asked about what situations would result in product recall.

Docket Number, Name, Affiliation	Comments
77-5-038 (continued)	43. Questioned how the conflict between NIOSH certification of sound level meters (Type 5-2A), which do not provide C-scale readings, and the use of NRR to determine compliance, would be resolved. 44. Requested information on the status of NIOSH's voluntary certification program and the compatibility of the two programs. 45. Asked for clarification on Section 211.2.4-3 concerning the latitude to either affix labels or print on packages. 46. Asked what parameters were being considered for requiring Compliance Audit Testing. 47. Questioned the conditions under which prior year's label verification data would be accepted for current year's production. 48. Questioned how EPA plans to handle the matter of private label manufacturing, as it relates to labeling requirements. 49. Suggested that the amount of information proposed for the label is excessive and that EPA should design a label that would not require redesign and enlargement of the product package. 50. Gave examples of redundant label information, such as company name, location, and product model number. 51. Felt that color contrast is unnecessary if the label is legible. 52. Quoted Section 10 of the Administrative Procedures Act 5 U.S.C. S706(2), and suggested that the proposed regulations were legally as well as technically unsound. 53. Suggested that regulations concerning specification of label content, EPA's inspection authority and recordkeeping requirements of manufacturers exceed the authority conferred on EPA by Congress. 54. Pointed out that Section 8 of the Noise Control Act of 1972, 42 U.S.C. S4907(b), requires only a label giving notice of the hearing protector's effectiveness in reducing noise.

Docket Number, Name, Affiliation	Comments
77-5-038 (continued)	55. Stated that there is no statutory basis for the requirement that the label contain information beyond the noise-reducing effectiveness notice, such as the EPA logo and especially the removal prohibition statement, noting that Congress usually expressly specifies such requirements.
	56. Suggested that the proposed enforcement provisions magnify the manufacturer's requirements as stated in Section 13 of the Noise Control Act.
	57. Cited specifics in the proposed rulemaking which exceed the requirements of Section 13 by requiring manufacturers to admit EPA inspection officials to their private facilities for inspection and monitoring activities.
	58. Cited examples of proposed noise labeling regulations which, in ISEA's opinion, lack a rational basis and constitute an abuse of discretion.
	59. Pointed out that the proposed regulations may be unconstitutionally vague, noting that the grounds for a cessation order are ill-defined, particularly the term "substantial." (211.1.9(f)(2))
	60. Indicated that a public hearing on Subpart B is constitutionally required.
-039 Thomas J. Woods President Aural Technology, Inc. (9/19/77)	1. Requested exception to the method of testing under Subpart B as the methodologies in Sec. 211.1.3(b) and (c) are not appropriate for the device vented through a patented Resonance Decay Acoustical Filter.
	2. Reported that the vented device has been tested under a procedure described as "An Objective Evaluation" by the University of Oregon, Health Sciences Center.
	3. Requested that the objective evaluation method be approved for vented devices to avoid competitor discrimination.
	4. Expressed support for the noise labeling requirements and offered full cooperation to EPA.
	5. Attached promotional literature for the vented device.

Docket Number, Name, Affiliation	Comments
77-5-039 (continued)	6. Attached correspondence with Dr. Jack A. Vernon, Director, Department of Otolaryngology, Kresge Hearing Research Laboratory, University of Oregon Health Sciences Center. Dr. Vernon (a) strongly objected to EPA reliance on ASA STD 1-1975 as the only way to measure the effectiveness of hearing protectors; (b) supported objective testing procedures; and (c) reported on the disadvantages of ASA STD 1-1975.
	7. Attached Dr. Vernon's vita.
	8. Attached report, authored by Dr. Jack Vernon, evaluating the product by the objective evaluation method.
	9. Attached ANSI Z24.22-1957 test data for the unvented model of the custom molded ear protector.
-040 Charles S. Shoup General Manager E-A-R Corporation	1. While agreeing with the principle of the program, Mr. Shoup noted that E-A-R's costs for its implementation total nearly one-fourth of EPA's estimates for the entire industry.
	2. Pointed out that E-A-R's NRR rating under ANSI S3.19-1974 is 29, but requested the report of an approximate range to avoid changes in printing.
	3. Felt that the label size and information requirements proposed pose extremely unreasonable demands on the manufacturers of insert devices, because of the small size of the packaging.
	4. Urged that only the NRR rating be included on each package and that the label and octave band data be prominently lettered on the dispenser or master package and on technical and/or sales literature.
	5. Proposed that consideration be given to different regulations concerning industrial and commercial sales.
	6. Suggested that month and year of production information is not useful and that codes on dispenser boxes should be sufficient for EPA's purposes.

Docket Number, Name, Affiliation	Comments
77-5-040 (continued)	7. Disagreed with methods for determining compliance in that derating becomes a measure of the risk the manufacturer is willing to take.
	8. Suggested that manufacturers be able to choose the lab used for compliance audit testing.
	9. Felt that the requirement for two Federal tests and potential repeated tests is extremely unreasonable and arbitrary.
	10. Suggested that protectors be considered in compliance if the one-third octave bands were within one standard deviation of the Federal Compliance Audit Test.
	11. Reported no suggestions for the error boundaries applicable to the NRR.
	12. Suggested that if non-compliance occurs, the manufacturer be required only to relabel all new protectors produced, allowing a reasonable time for conformance.
	13. Pointed out that Part 211.2.9-4(b) should be stricken since the information is confidential and proprietary.
	14. Pointed out that more than six months would be required to comply with the regulations as they currently stand.
	15. Felt that EPA should show due cause when requiring Compliance Audit Tests.
(letter of 1/27/77)	16. Pointed out that the printing of information on an individual protector was not practical in terms of hygiene, legibility, or cost-usefulness.
	17. Provided several points of information on their protectors requested by EPA.
-041 John F. Dickey, Attorney Energy and Environment Division DuPont Company	1. Cited references to dispel the negative bias contained in the fourth paragraph of the NPRM Introduction concerning the efficiency of hearing protective devices.

Docket Number, Name,
Affiliation

Comments

77-5-041 (continued)

2. Suggested adoption of the original rating system proposed by NIOSH, contained in Appendix A of Section I of "Criteria for a Recommended Standard in Occupational Exposure to Noise" (NIOSH 1972).

3. Pointed out that the EPA program will require a large amount of redundant effort, and suggested that new testing and labeling be limited to new products.

4. Recommended that the simplicity of a single number rating should never be used to obscure the performance effectiveness of a device over individual bands of frequency.

5. Recommended that the NRR be based only on differences between A-scale weighted levels rather than C-scale levels.

6. Pointed out that annoyance factors should be considered separately from "potential impairment" factors in the rating system.

7. Recommended comparison testing of third octave band measurements and standard octave band measurements to determine if costly third octave band requirements are needed.

8. Attached a document entitled "Real-Ear Sound Attenuation Characteristics of Hearing Protective Devices Available Through Federal Supply Channels" as coordinated with the U.S. Army Technical Bulletin TB MED251, 25 January 1975.

9. Attached pages I9 through I13 of Section I in "Criteria for a Recommended Standard in Occupational Exposure to Noise" (NIOSH, 1972).

10. Attached pages 1 and 2 of HEW Publication No. (NIOSH) 76-120, "List of Personal Hearing Protectors and Attenuation Data" (Sept, 1975).

11. Attached selected pages of articles appearing in trade and safety journals. These include: "Hearing Protection and the Employee," "Personal Ear Protection," and "Getting Employees to Wear Hearing Protection."

Docket Number, Name, Affiliation	Comments
77-5-042 Julian Pawlina Chief Engineer Taylor Products	1. Requested further information on the proposed regulations.
-043 Michael J. Percy Senior Urban Planner City of Mountain View, California (Also 77-8-172)	1. Opposed the use of a numerical or symbolic rating scheme which required consumers to refer to additional materials to interpret its meaning.
	2. Suggested that the label be direct and "state the amount of decibel reduction that would be achieved by a given noise protection device or the number of decibels that the machinery produced."
-044 Roland Westerdal President Bilsom International, Inc. (letter dated 9/7/77)	1. Asserted that the EPA regulations confuse the identity of the purchaser and the end user, who are seldom the same in the hearing protector market.
	2. Noted that the commercial buyer does not inspect the individual product package and for that reason, there is no need for labels on the product package and the product or its carrying case. In addition, if the carrying case is not the package and is therefore not visible or accessible at the time of purchase, the issue is how the label can be of use to consumers.
	3. Recommended that the necessary information be provided at a location defined flexibly to relate to the product, its package, and the reality of the sales transaction.
	4. Claimed the minimum label size requirement is rigid and impractical, in that it exceeds the size of many of the products and their packages.
	5. Recommended flexibility in label size requirement, because of the range in size of products and the need to vary the label location to suit the sales transaction.
	6. Suggested there was no logical distinction between supporting information and label information and that they should be treated with equal flexibility.

Docket Number, Name, Affiliation	Comments
77-5-044 (continued)	7. Stated that the proposed regulations do not recognize the influence of a variety of laboratory conditions on the test results and that it would be unjustified and unfair to impose on manufacturers liability for test variations due to these limitations. 8. Maintained that submittal of information from manufacturers concerning actual and planned production volume should not be required, due to its sensitivity and irrelevance to the Agency's goals. 9. Pointed out that pre-approval of labels is unnecessary and would result in delays (211.2.10-3). 10. Recommended that manufacturer's verification of label information be required only if there is a negative change in the level of protection afforded and not on an annual basis. Therefore, deletion of 211.2.10-8 was suggested. 11. Criticized the choice of a 0 to 31 dB range, noting that according to their calculations the best protector tested in accordance with S3.19-1974 had less than 25 dB attenuation. He indicated that the documentation for whatever range is used should be discussed at a public hearing. 12. Outlined several factors contributing to the cost of the program and suggested that nation-to-nation requirements should also be reflected in any analysis of costs. 13. Pointed out a conflict between the general provisions and the proposed hearing protector labeling regulations with respect to who will bear the cost of Compliance Audit Testing and suggested that these costs should be borne by the Administrator and so stated in the final regulations or an accompanying statement. 14. Requested a 12-month rather than a 6-month effective date. 15. Pointed out the need for coordination with respect to the impact of the program on imported products.

Docket Number, Name, Affiliation	Comments
77-5-044 (continued)	16. Complained about lack of consideration of special problems facing an international company and suggested the scheduling of a public hearing to discuss the hearing protector regulations and related general provisions.
	17. Resubmitted to the public docket Mr. Westerdal's letter of May 10, 1977, which was originally assigned docket number 77-5-001 and is summarized therein.
-045 Thomas J. Woods President Aural Technology, Inc.	1. Expressed thanks to EPA in connection with his appearance as a witness at the San Francisco hearing.
	2. Expressed confidence that the industry would support a reasonable labeling requirement from a single agency such as EPA rather than numerous requirements from many agencies.
	3. Cited an enclosed copy of a competitor's catalog advertising a protector in an allegedly unsubstantiated and misleading manner.
-046 Stuart M. Low, President Flents Products Company, Inc.	1. Expressed pleasure at having the opportunity to testify at the September 16 public hearing.
	2. Expressed concern about the labeling of products sold in bulk and some of the special packaging they use in consumer markets.
	3. Expressed concern about the proposed rules as they would affect imported hearing protectors.
	4. Suggested a meeting in the future.
-047 R. Waugh Psychoacoustics Section National Acoustic Laboratories Australian Department of Health	1. Expressed opinion that under the proposed method of calculating the NRR, user will be overprotected with unnecessarily heavy and uncomfortable devices.
	2. Using a hypothetical method described in an enclosed paper, he calculated that the NRR has an overall protection rate of 99.7 percent instead of 98 percent, but removal of the 3 dB "spectrum" brings this figure to 97.5 percent.

Docket Number, Name, Affiliation	Comments
77-5-047 (continued)	3. Noted that the objective of 97-98 percent is much greater than the objectives set by the U.K., W. Germany or Australia, which have adopted a mean-minus one standard deviation for a protection rate of around 80 percent. 4. Suggested re-examination of the need for the 3 dB "spectrum" correction in the NRR calculation. 5. Included two of his papers entitled: a. "Investigation of South Level Conversion as a Means of Rating Ear Protector Performance," American Industrial Hygiene Association Journal, April 1976, 239-245. b. "Calculated In-Ear A-Weighted Sound Levels Resulting from Two Methods of Hearing Protector Selection," Ann. Occup. Hyg.,19, 1976, 193-202.
-048 D. Lambert Naval Ocean Systems Center	1. Cited a number of suggested changes and typographical errors in the NPRM (42 FR 31730). 2. At p. 14, suggested that EPA may want to include "desire" for protection under "comfort." 3. At p. 27, 1.6, suggested use of a term other than "displacements" to avoid confusion. 4. Stated, re: p. 31, bottom line, that "the dB(A) noise reduction" is an incorrect phrase, suggesting "the A-weighted noise-reduction in decibels" instead.
-049 Dr. G. L. Cluff, Director Tri-Utility Hearing Conservation Program Salt River Project	1. Endorsed use of a single number label for personal hearing protectors. 2. Suggested that the single number label would provide practical information for comparing attenuation characteristics of hearing protectors. 3. Suggested that the single number label could also find practical field use in cases where individuals needed to determine whether a given protector model would provide adequate protection in a given noise hazard area.

Docket Number, Name, Affiliation	Comments
77-5-049 (continued)	4. Asserted that the level of protection afforded the user of a given PHP model could be obtained by subtracting the "R" value, determined through procedures defined in the NIOSH 76-120 report, from the dBA sound level. 5. Suggested that the R value be used as the product label. 6. Reported on calculations of the R value for personal hearing protectors as a function of nine different idealized noise spectra. 7. Attached data supporting the notion that the scope of the noise spectra significantly affects the R value achieved by the personal hearing protector. 8. Recommended that the reported R represent the worst case performance of the personal hearing protector and that, according to their data, this would be a -12 dB per octave slope. 9. Suggested that a negative slope in the neighborhood of -6 to -12 dB be adopted as the standard slope for the determination of the R value of the personal hearing protector. 10. Expressed the opinion that PHP manufacturers' publication of octave attenuation characteristics, along with the standard deviation for the attenuation at each octave, was highly desirable.
-050 Thomas J. Woods President Aural Technology, Inc.	1. Requested status of ATI's 9/19/77 request for exception from testing for its vented device that cannot be tested under ANSI S3.19-1974 (ref: 77-5-033) since the firm was about to proceed on qualification for a new product.
-051L Kenneth Bridbord, M.D. Director, Office of Extramural Coordination and Special Projects NIOSH, Public Health Service, Center for Disease Control, DHEW	1. Noted that "manufacturer" is not defined (211.2.1) 2. Based on its experience with manufacturers' testing, NIOSH felt "that relying on test facilities which are manufacturer-owned or manufacturer-selected is an inadequate enforcement technique. NIOSH certifications or approvals are based on test data generated in NIOSH laboratories. We therefore suggest that EPA rely on NIOSH test data once we have established a certification program for hearing protective devices."

Docket Number, Name, Affiliation	Comments
77-5-051L (continued)	3. Pointed out a typographical error at 211.2.4-1(c), replacing "to" with "is" before the numeral "0".
	4. Suggested that attenuation for each position of headband device use should be provided to the user.
	5. Listed a number of items for inclusion with supporting information, consisting mainly of instructions for proper use and fit, expected attenuations, and methodology, including a reference of where methods could be found to predict the wearer's noise exposure when the noise field is described in different ways.
	6. Noted that NIOSH is considering other important performance characteristics of protectors beyond attenuation for its certification program.
	7. Suggested wording for a supporting explanation of the NRR.
	8. Suggested that the manufacturer provide the exact mean attenuation and standard deviation on which the labeled NRR is based.
	9. Suggested use of a one-sided, two sample t-test applied at each 1/3 octave band to determine "significantly less" at 211.2.6 for compliance purposes and recommended rewriting of 211.2.12-6 and 7 based on this point and point 8 above.
	10. Noted NIOSH testing indicates less (50-65 percent) attenuation for three protectors under field conditions than under laboratory conditions, implying inadequate fits.
	11. Pointed out NIOSH requirements for quality control in its certification program (Subpart B of 42 CFR 82).
-052L Elliot H. Berger Acoustical Engineer E-A-R Corporation	1. Responded to requests for information from EPA arising from meeting.
	2. Enclosed data on an obsolete protector comparing results of Z24.22 and S3.19 testings, and enclosed test result data for a test conducted on an obsolete protector by four different laboratories.

Docket Number, Name, Affiliation	Comments
77-5-052L (continued)	3. Noted additional cost estimates for a six-month period as opposed to a "more reasonable 12-18 month compliance period," as "substantially greater than $50,000." These costs consist mainly of packaging, scrapping or modifying existing inventory, conversion to new packaging, and lost sales. 4. Enclosed copies of current consumer information literature.

RELEVANT COMMENTS:
GENERAL PROVISIONS DOCKET 77-8

77-5-060
Mr. Stuart Low, President
Flents Products Company
(Also 77-8-904-WH)

Oral Statement at Washington, D.C. Public Hearing -- 9/16/77

1. Mr. Low objected to the handling of Subparts A and B by EPA with particular reference to the lack of distinction given them by EPA and the time obstacles for comments on Subpart B, directly affecting his firm as a manufacturer of hearing protectors. (129-130)

2. Mr. Low maintained that labeling for retail hearing protectors would not accomplish the desired results because of the small size of the devices, the public's lack of awareness and the public concern with comfort rather than a technical acoustic rating descriptor. (131-133)

3. Although Mr. Low had no objection to ASA's test No. 1, Standard of 1975, per se, he did urge caution about the use of such a relatively new procedure. (134-135)

4. With reference to Sections 211.1.1 and 211.1.9 Mr. Low noted that the definition of "manufacturer" for the purposes of importation remains unclear; does "manufacturer," for example, encompass "assembler"? In addition, rules for importers have yet to be articulated. (135-137)

5. Mr. Low suggested allowances for sufficient lead time in the implementation of the labeling program to account for importation and manufacturing difficulties. (137-138)

6. Referring to Section 211.1.4, Labeling Content, Mr. Low pointed to excessive information requirements for earplugs, much of it duplicating contents on the product's packaging, and also objected to the large size of the proposed labels, requiring larger and costlier packaging for the earplugs. These requirements, Mr. Low concluded, are unduly burdensome to the industry, given the low cost of making ear plugs.

7. Referring to Section 211.1.5-8, Mr. Low objected to the requirement to affix labels on each individual product, since many of his firm's sales are in bulk lots in cost-saving packages. Mr. Low also inquired about what could be pasted on as opposed to less costly printing of a label. (141-143)

8. Referring to Section 211.1.9, Inspection and Monitoring, Mr. Low objected in light of unpleasant experiences with New York State regulations, to the "extraordinary" inspection powers afforded to EPA, and suggested two paragraphs (pp. 146-147) be appended to the regulations circumscribing EPA cessation of production orders. (144-147)

9. Mr. Low objected to the lack of hearings on the hearing protector proposals, Subpart B, and urged a dialog with EPA and his industry leading to a more voluntary program. (147-149)

Responses to Questions from EPA Panel: Mr. Thomas

10. Mr. Low commented that he did not oppose the new ANSI S3.19-1974 standard test but rather was concerned about its relative novelty for testing purposes. (150-156)

11. Mr. Low expressed concern over placing rating labels on both his product's packaging insert and on the box itself, which he felt would be a costly procedure. (156-158)

12. Mr. Low suggested that EPA consider the differences for labeling purposes in hearing protectors marketed for individuals versus those sold in bulk packages to industry. (159-164)

Dr. Shutler

13. Mr. Low suggested more highly articulated enforcement language in the regulation, vesting cessation-of-production authority clearly in the Administrator, to inform enforcement offices of the limits of their discretion. (165-168)

Mr. Kozlowski

14. Mr. Low pointed out differences in costs, marketing and packaging of ear muffs and ear plugs for labeling purposes but preferred to defer to Industrial Safety Equipment Association's comments on the ear muff matters. (168-170)

Mr. Cerar

15. Mr. Low received clarification from Mr. Cerar that a domestic assembler of imported components would be considered a domestic manufacturer for purposes of the regulations. (170-171)

16. Mr. Low expressed concern over possible delays in implementing Import Section 9 through Treasury Department regulations, which have yet to be issued. (171-173)

Mr. Feith

17. Mr. Low pointed out that a 12-422 attenuation test costs around $2,000, and labeling might add 80 percent to his container costs. (173-176)

77-5-061
Thomas Woods
President of Aural Technology
Also 77-8-949-SH

Oral Statement at San Francisco Public Hearing -- 9/22/77

1. Mr. Woods, manufacturer of protective hearing devices, expressed support for the labeling program and described a case where a person exposed to noise at a recording company suffered extreme hearing loss. (178-179)

2. Mr. Woods expressed concern about the lack of interagency coordination and thus the difficulty of satisfying different regulations. He also expressed concern about the economic impact of the testing costs and objected to the authority of the Administrator to order a compliance audit even when there was no evidence of noncompliance. (180-183)

3. Mr. Woods described the content of his company's proposed brochure. He stated that a pressure-sensitive label which could be peeled off would cost about 3 cents per unit -- a reasonable price for a device costing $5.03/unit. The cost of printing the sample brochure he showed to the panel would be less than 1 1/2 cents per unit, based on printing 100,000. Costs for preparing camera-ready copy and graphics would be about $10,000, of which $7,500 would be nonrecurring expenses. The label could be done economically, he asserted. His label also contained information on how to properly use the ear protectors. (183-187)

Responses to Questions from EPA Panel: Mr. Thomas

4. Mr. Woods suggested that most companies in the hearing protective device industry would not be reluctant to publish the noise attenuation properties of their products on a label, though he admitted some would hesitate to do so. (190-192)

5. Mr. Woods suggested that the "label" information be required in advertisements directed at industrial consumers of hearing protectors. (193)

6. Mr. Woods said the name of the company which introduces the product into commerce should be on the label and not the original manufacturer. Annual reports represent a means of tracking down the true manufacturer. Mr. Woods did not see any problem in repeating the company's name both on the packaging and on the label. (196-200)

7. Mr. Woods felt the EPA logo should be on the label but noted that this carries with it an explicit endorsement of the validity of the information by EPA. (201-202)

8. He suggested that it is important for EPA to require on the label information about the likely degradation of the attenuation capabilities of hearing protective devices. (204-206)

77-5-062
Mr. and Mrs. Crozier
French Laboratory
(Also 77-8-954-SH)

Remarks from the Floor at San Francisco Public Hearing -- 9/22/77

1. Mr. Crozier, a manufacturer of custom-molded hearing protectors, suggested that labeling take into account factors like comfort, hygiene properties, and the appropriate fit. He noted that an attenuation rating based on laboratory subjects is meaningless (and misleading to consumers), since there are variations in the structure of the human ear and protectors will not function properly unless they are built to correspond to these variations. (325-326)

2. Mr. Crozier suggested a statement for the label (or brochure) which emphasizes that the amount of attenuation an individual will derive from the product is based on a proper fit. Factors affecting the "fit" are ear canal configuration, haircut, eyeglasses, etc. (330-332)

3. Throughout Mr. Crozier's discussions with EPA panel members, questions were raised about the validity and reliability of test procedures used by laboratories to rate hearing protectors (e.g., ASA 1-1975). (326-334)

4. Mr. Crozier explained that even if certain information cautions the user about the need for a proper fit, there are serious problems because of the average person's ignorance about what constitutes a "proper fit." (336)

5. Mrs. Crozier suggested there may be a serious problem raised by fraudulent activities of test labs, working in collaboration with manufacturers. (341)

6. Mrs. Crozier cited the problem of an inaccurate label remaining on a product which has undergone repairs affecting its noise properties. (343)

77-5-063
Mary O'Neal Broida
(Also 77-8-047)

1. Requested information on the availability or future development of ear protectors which will substantially reduce noise at all frequencies.

2. Commented that she is trying to find "ear protectors which will eliminate or reduce noise for people who are trying to sleep in noisy environments."

77-5-064
Morris Tenenbaum
(Also 77-8-051)

1. Expressed approval of product noise labeling program.

2. With respect to the effectiveness of hearing protectors, Mr. Tenenbaum cited the following publication and noted that the quoted effectiveness rating numbers ranged from 6 to 47:

National Institute of Law Enforcement and Criminal Justice, Law Enforcement Assistance Administration, U.S. Department of Justice (NILE-CJ-0101.00, April 1976), Selection Guide to Hearing Protectors for Use on Firing Ranges.

77-5-065
John Connolly
(Also 77-8-052)

1. Expressed support for labeling of hearing protectors.

2. Noted effects of noise on the tuning of musical instruments and professional musicians.

77-5-066
James Bogar
(Also 77-8-058)

1. Expressed strong opposition to the labeling provisions for hearing protectors.

2. Questioned the meaning of the rating number and asserted that noise-reducing products and noise-producing products cannot be labeled in the same manner.

77-5-067
Mrs. Vernon Wall
(Also 77-8-069)

1. Expressed interest in and support of the program.

2. Requested assistance in identifying effective hearing protectors and their marketing source.

3. Complained about the ineffectiveness of certain materials and earplugs in reducing noise.

77-5-068
Larry W. Potter
Standards Officer
Kentucky Department of Labor
Occupational Safety and Health

1. Commented on the problem of evaluating hearing protectors, noting that studies have indicated that manufacturers' attenuation values are seldom accurate in the actual work environment. Possible reasons for the discrepancy include improper fitting or wearing and the determination of attenuation values under ideal conditions.

77-5-068 (Continued)	2.	Recommended therefore that hearing protector labels contain a disclaimer informing potential purchasers "that the actual attenuation values as listed by the manufacturers can be affected by improper fitting or wearing . . . " and "that the manufacturer's values represent the maximum attenuation under ideal conditions, with the insert-type hearing protectors fitted by individuals trained in this procedure . . . "
77-5-069 K. O. Tooker, President Plasticast Laboratories, Inc.	1.	Asserted that the sound attenuation of custom-molded ear protectors will vary from one individual to another depending on stiffness of ear tissue and other factors. Tests have indicated attenuation varying from 18 to 22 decibels in the range of 300 to 1000 Hertz and from 28 to 35 decibels in the range of 3000 Hertz and beyond.

ORAL TESTIMONY

PUBLIC MEETING ON LABELING REGULATIONS FOR HEARING PROTECTORS

(Crystal Mall, Crystal City, Virginia, 13 December 1977)

Docket No.	Person	Organization
77-5-101	Stuart M. Low, President	Flents Products, Inc.
77-5-102	Frank J. Lotlo	Mine Safety Appliances Company
77-5-103	Ronald J. Cox	Wilson Products Division of ESB
77-5-104	Elliot Berger	EAR Corporation
77-5-105	Roy Fleming	NIOSH
77-5-106	John M. Ruffner, President	Plasmed, Inc.
77-5-107	Earl W. Broker	Norton Company, Safety Products Division
77-5-108	William Newcomb	Norton Company, Safety Products Division
77-5-109	Frank E. Wilcher, Jr.	Industrial Safety Equipment Association
77-5-110	James T. McCallum, Jr.	Reynolds Metals Company

This public meeting was less structured than a formal public hearing in that commenters were allowed to make more than one statement. There were free exchanges of ideas between commenters and Agency panel members, as well as exchanges of ideas among commenters. Therefore, all statements from commenters and panel members are listed as they occurred. Docket numbers were assigned to commenters in their order of initial appearance.

The page number of the transcript of the public meeting on which the statement occurs is noted in parentheses at the end of the statement.

DOCKET SUMMARY FOR PUBLIC MEETING

Commenter (Doc. No.)	
Mr. Low (101)	Pointed out that the requirements place a burden on the manufacturers of hearing protectors in terms of labels, printing costs, and higher costs for larger boxes, particularly for the insert type of protectors. (17)
	Pointed out that the labeling requirements for hearing protectors are more severe than those required by the Mining Enforcement Safety Administration on respirators, which are often used in life and death situations. (18)
	Pointed out that in the industrial market, which is different from the consumer market, the ultimate user does not purchase the hearing protector and therefore questioned that the users need to have this information, given that they have no control over the purchase decision. (18-19)
	Questioned the need for labeling information on earplugs used by some swimmers. (20)
	Questioned whether imported products would be given treatment equal to that of domestic products under Section 9. (20-21)
Mr. Lotlo (102)	Questioned regulations concerning the importation of hearing protector components. (24)
Mr. Low (101)	Reported that, according to his informal survey of laboratories, there are no more than three laboratories in the country currently able to perform the required test. (25)
	Due to the limited number of, the limited capacity of, and the scheduling within testing agencies, Mr. Low suggested that the 6 month compliance period be extended to no less than 12 months and possibly to 18 months. (25-26)
Mr. Lotlo (102)	Reported on a survey of psychoacoustic laboratories conducted by the National Bureau of Standards and suggested that only one of the three laboratories found to do psychoacoustic testing did contract work for manufacturers. (27)
	Mentioned that testing requires laboratories which are well-versed in psychoacoustics. (29)
Mr. Cox (103)	Expressed the opinion that testing laboratories require trained listeners in addition to appropriate facilities. (30)

Commenter (Doc. No.)	
Mr. Low (101)	Noted the distinction between overall capacity to do testing and ability to do testing in a reasonable time period. (30-31)
	Indicated that the cost of testing which could range from $1200 to $2000, weighs more heavily on the smaller company. (31)
	Suggested that consideration be given to the possibility of using small package inserts to give notice to the potential users of the insert-type hearing protectors. (31-32)
	Citing bad experiences in New York, Mr. Low felt that manufacturers deserved protection against inexperienced and perhaps unreasonable inspectors. (33-35)
	Suggested provisions which grant only the Administrator the authority to order a manufacturer, distributor, or user to cease distribution or use of a product, and then only in writing with a copy sent to the manufacturer by registered mail. (34)
	Mr. Low mentioned that the cost of inserts to packaging would vary according to the amount of information provided on the insert, but that they would be under three cents apiece. (35)
Mr. Cox (103)	Interjected that the cost of packaging changes, which depends upon the rigor of packaging requirements, could conceivably exceed the cost of the product in the package. (36)
Mr. Low (101)	Emphasized that a given product is often packaged in several ways, each having its own limitations in terms of labeling. (38)
	Objected to any requirement for labels affixed to individual protectors or their carrying cases when they are sold in bulk. (41)
	Asserted that the size requirements for the labels make impossible their application on one particular transparent insert-type protector box currently produced. (42)
Mr. Berger (104)	Suggested that disposable or semi-disposable hearing protectors packaged in bulk be treated differently from other hearing protectors with respect to labeling. (43)
Mr. Cox (103)	In response to a question, Mr. Cox agreed that there would be no "label size" problem with respect to the muff-type protector. (44)

Commenter (Doc. No.)	
Mr. Low (101)	In response to questions by EPA panel members, Mr. Low reported on his testing costs and his procedures for testing imported products. (47-50)
	Mr. Low discussed educational and sales literature as a substitute for labels in the industrial market. (51-52)
	Mr. Low indicated that he knew of no satisfactory or reliable objective tests for the insert-type protector. (54-55)
	In response to questions by EPA panel members, Mr. Low provided information about the kinds of products he imports and the means through which he obtains test data on these products. (55-57)
Mr. Berger (104)	Submitted a mock-up label which suggests that the 1-1/2 x 2 inch label cannot accommodate the required type size. (57)
Mr. Fleming (105)	Reported on a NIOSH study which compared the attenuation values of hearing protectors obtained through a field test at four industrial sites in Kentucky with those obtained in the laboratory under the old ANSI standard. According to the study, workers were not getting the dBA reduction that would be predicted through the ANSI laboratory test procedures. The implications of the study were that these workers were not wearing the protectors the way trained test subjects do and/or that they had significantly different ear canal structure.(59-68)
	Mr. Fleming reported that NIOSH was in the process of developing a certification program for hearing protectors. (69)
Mr. Cox (103)	Reported that Wilson Products had data comparing products under the old and new test standards. (69)
Mr. Fleming (105)	Mr. Fleming briefly discussed a short, subjective test which was used as a check on the ANSI test system. (77-78)
Mr. Berger (104)	In a discussion concerning criteria for trained subjects, Mr. Berger said that trained subjects were those who had experience with the program. (79)
Mr. Cox (103)	Mr. Cox reported that while he couldn't quantify the variability, the results of tests by different laboratories on similar devices were not the same. (80)

Commenter (Doc. No.)	
Mr. Fleming (105)	Suggested an adjusted NRR which takes into account the variability of the mean itself. (81)
	In response to a question, Mr. Fleming suggested that the adjusted NRR would be even lower if the larger standard deviations found in field tests were taken into account. (82)
Mr. Berger (104)	A 10 dB range of means was obtained on one type of plug tested at several laboratories three to four years ago. (83-84)
	Pointed out that the NRR range of 1 to 31 would more likely be on the order of 0 to 35 using ANSI S-3.19-1974 data. (84)
	Reiterated that a differentiation should be made between disposable and reusable insert protectors. (85)
	Felt that the regulations, rather than standardize the reporting of data, create a gambling situation for the manufacturer in that the manufacturer determines the risk he is willing to take for noncompliance. (85-86)
	Suggested that some standardized method for comparing government certification test results and reported data be adopted. He felt that if the government test and the reported data were within one standard deviation, then probably the data should be determined to be in compliance." (86)
	Emphasized the need to consider the problem of determining the variability of the NRR rating. (86)
	Suggested that Section 211.2.9(4)(b) concerning EPA's right to know about production data for any particular period of time be stricken from the document since the need for such data is not demonstrated. (86-87)
	Suggested that code numbers be substituted for the dating of protectors, given that presumably the purpose of the dating requirement is to allow the manufacturer the ability to recall a specific product that has been determined to be out of compliance. (87)
	Suggested that information on an 8-1/2 x 11 inch sheet of paper contained in each carton of 200 units would supplement the short form instructions on each individual protector package and would be a suitable means of supplying data to the end users of the products -- both individual protector users and industrial safety officers. (87-88)

Commenter (Doc. No.)	
	Has found no correlation in decibel changes between an objective test using an artificial ear and a subjective test. (88)
	Suggested that any NRR derating brought about by studies showing difference between laboratory and field tests be done on a protector-by-protector basis. (88-89)
Mr. Berger (104)	In response to a question by a member of the EPA panel, Mr. Berger suggested that it would be inappropriate to provide production data since it would then be available to competitors. (90-91)
Mr. Berger (104)	Expressed the opinion that additional testing would be required to determine the correlation between objective and subjective tests. (91-92)
Mr. Berger (104)	Suggested that one method for discounting the variance between laboratories would be to retest the product at the laboratory which did the original testing, assuming that the laboratory was on a government certified list of laboratories. The product would be found in compliance if its new mean was not more than one standard deviation lower than the prior reported mean. (95)
Mr. Ruffner (106)	Reiterated that the cost of going to court to contest the Agency's remedial action is a staggering sum for a small manufacturer. (97-98)
Mr. Low (101)	Expressed concern about adopting an objective test for the muff-type protector since this would give the muff-type protector an advantage in the market place in the future. (99-100)
	Expressed concern over potential bias resulting from manufacturers using their own test laboratories instead of independent laboratories. (100-101)
Mr. Ruffner (106)	Maintained there was a conflict between the defense medical purchase description and the EPA labeling requirement. (103-104)
	Stated that the manufacturing costs to manufacturers selling in bulk to other firms will more than double under the proposed regulations and discussed some labeling-related manufacturing costs. (104-105)
	Pointed out that ear plugs may go through four levels of distribution before they reach the ultimate consumer. (104-105)

Commenter (Doc. No.)

Discussed the costs involved in the change of an etching on a molded earplug and reported that the total cost would be about $1600 per mold. (105-106)

Asserted that his insurance premiums for product liability would increase to about $50,000 with the implementation of labeling requirements. (106)

Noted that there was no way to determine whether the ultimate user of a given earplug produced by his firm was using it for swimming protection or hearing protection. (107)

Questioned whether tests would have to be duplicated by both manufacturing and distributing firms or whether one test would satisfy the Agency. (108-109)

Pointed out that exported earplugs are often repackaged by a broker prior to export, and that contracts with various foreign governments could not be met if the regulations governing exported products were implemented. (109)

Objected to the perceived unfair advantage given to ear muff protectors because the cost of labeling ear muffs relative to the cost of the ear muff itself is inconsequential. (109-110)

Suggested that information provided on an 8-1/2 by 11 inch sheet of paper would be cheaper than box imprinting or adhesive labels and would pose no problems. (110)

Expressed "no inhibition on (his) part to supply any test data to any user." (110)

Feels strongly that the $300,000 figure calculated by EPA as the regulation's cost to the manufacturer is totally unreasonable. (111)

Mr. Ruffner described the system by which earplugs are exported and indicated the problems involved in knowing whether a given earplug will reach a foreign market or remain in the domestic market. Mr. Ruffner also explained that his products may be repackaged three or four times. (112-114)

In response to a series of questions, Mr. Ruffner explained that he provides his purchasers with photocopies of test results carried out on five sizes of randomly-selected earplugs, and that these tests have been run five times in seven years. (115)

Commenter (Doc. No.)	
	In response to questions by EPA panel members, Mr. Ruffner explained that his firm has no routine quality control checks to determine if and how content variations between batches of plastic affect the acoustic properties of his earplugs. He noted that the specification sheet distributed with the earplugs relates to the technical performance of an arbitrary batch and not the batch from which they were produced. (117-118)
Mr. Broker (107)	Mr. Broker suggested that the labeling requirements be placed on the last handler of the product prior to the end user or consuming company. (119-120)
	Indicated that if he purchased protectors from another manufacturer (e.g., Mr. Ruffner) who already performed the required tests and provided him with a Xerox copy of the results, he would not run any additional tests (assuming he was satisfied with their accuracy). (121)
Mr. Low (101)	Raised the issue of whether the person doing the testing would allow his customer to release the results to another manufacturer for use by that manufacturer. (121)
Mr. Ruffner (106)	Raised a question as to the professional ethics of photocopying original-source data and sending it to another manufacturer. (121)
Mr. Low (101)	Reiterated the idea that the earplug is able to compete with the earmuff because of its low price and that a substantial price increase because of labeling would render it less competitive. (121-122)
	Pointed out that the label would not necessarily identify the actual manufacturer, given current marketing practices. (123)
	Mr. Low indicated that he was inclined to use original test results rather than subject a product to additional testing, provided the results are available. (123-124)
Mr. Ruffner (106)	Explained batch-to-batch quality control procedures run according to Military Standard. (126-127)
Mr. Low (101)	In relation to problems with the Defense Supply Agency and other government agencies, Mr. Low commented that the change of a specification is often a 2 or 3 year job and that contracts are often held up for this reason. (128)

Commenter (Doc. No.)	
Mr. Newcomb (108)	Suggested that artificial objective testing is inappropriate for anything other than quality control, even for the muff-type protector. (129-130)
	Responding to questions from the EPA panel, he indicated that hairstyles and the wearing of glasses affect test results but are not taken into account systematically in the subjective testing. (130)
Mr. Broker (107)	Expressed concern over the use of a single number rating system which emphasizes magnitude of performance as opposed to the reliability of performance. (132)
	Pointed out the advantages of non-linear hearing protectors and expressed concern over the fact that these would have an NRR of zero. (133)
	Supported different labeling requirements for the consumer product as opposed to the industrial product. (133)
	Mr. Broker explained that the nonlinear protector was packaged differently for different markets and that the information provided to consumers differed according to the particular market. (138-139)
Mr. Lotlo (102)	Expressed concern about requirements for embossing information on individual inserts, given the fact that different products come off the same hard tools. He suggested that, for monetary reasons, the labeling scheme should allow for something added to the product after the molding process so that the expensive process of repeatedly inserting different molds could be avoided. (139-140)
Mr. Low (101)	Pointed out that helmets and special muff attachments are often marketed together even though they are not made by the same manufacturer. (141)
Mr. Newcomb (108)	Mr. Newcomb explained that he tests his ear muffs on his own company's hats, but that other manufacturers make ear muffs that fit on several different companies' hats. (This situation raises the issue of whether or not a test is required for each combination of helmet and muff.)
Mr. Cox (103)	Summarized chains of distribution in both the industrial and consumer markets for his product. (143-147)
	Reported that the testing of one muff potentially worn in three positions with two different ear cushions, with or without a crown strap, could cost $24,000. (147)

Commenter (Doc. No.)	
Mr. Ruffner (106)	Cited market research studies which mentioned the reasons for buying hearing protectors as (1) comfort, (2) freedom in the work environment and (3) noise suppression effectiveness. (154-155)
Mr. Wilcher (109)	Questioned whether the proposed rule making would apply to both consumer and industrial markets. (156-157)
	Questioned how EPA would regulate the labeling of devices sold unpackaged in bulk quantities. (157)
	Asked about EPA's specific plans for developing an educational program to make purchasers aware of the NRR system, its purpose, applications and significance. (158)
	Inquired as to who would have responsibility for label verification testing and audit and compliance testing in the case of a device manufactured by one company and packaged or distributed by another. (160)
	Inquired about what situations would result in an order by the Administrator to recall or buy back products from purchasers. (160-161)
	Questioned the means by which EPA plans to resolve the conflict between pre-NIOSH certification of sound level meters, type S2A, which do not provide C-scale ratings, and the use of NRR to determine compliance. (161)
Mr. Lotlo (102)	Pointed out that an arbitrary scheme would not provide the customer with information as to whether a given protector would provide enough protection in his environment. (162)
Mr. Fleming (105)	Pointed out that it was possible to calculate the effective dBA level given knowledge of the NRR, the dBA level and certain correction factors. (163-164)
Mr. Wilcher (109)	Expressed concern about the compatibility of the EPA program with the pending NIOSH certification program. (166)
	Questioned whether manufacturers would, under Section 211.2.4-3, have the latitude to either affix a label or print the required information on the package itself. (167)
	Inquired as to the parameters being considered for requiring compliance audit testing. (168)

Commenter (Doc. No.)	
	Asked about the conditions under which EPA would not accept prior year's label verification data for current year's products. (169)
	Inquired about how EPA planned to handle labeling responsibility. (170)
Mr. McCallum (110)	Emphasized the importance of getting the information to the user. (170-171)
	Mr. McCallum explained his preference for offering employees a choice of protectors and cited his company's policy on this issue. (171-172)
Mr. Low (101)	Requested consideration of a 12-month implementation date since containers and other packaging materials are often ordered 15 months ahead of time. (173)

APPENDIX B

INDEX OF WRITTEN DOCKET SUBMISSION AND PUBLIC HEARING TESTIMONY

INDEX OF WRITTEN DOCKET SUBMISSIONS

Title: Noise Labeling Requirements-Hearing Protectors

Authority: Federal Register, June 22, 1977, Part IV, p. 31730

Number	Date	Company/Address	Writer
77-5-			
001	5/10/77	Bilsom International, Inc.	Roland Westerdal President
002	5/12/77	Bilsom International, Inc.	Marlene K. Olinger Administrative Assistant
003	6/28/77	Tasco Corporation, Inc.	Thomas A. Scanlon President
004	7/13/77	Flents Products Company, Inc.	Stuart M. Low President
005	7/18/77		Elizabeth Platt
006	7/21/77		Phillis H. Rosenthal
007	7/8/77	Aural Technology, Inc.	Thomas J. Woods
008		(omitted)	
009	8/1/77	Pennsylvania State University	Paul L. Michael, Ph.D. Professor of Environmental Acoustics
010	7/12/77		R.A. Smith
011	7/17/77		David Rankin
012	8/4/77		Kenneth R. Freitas
013		Indianapolis Speech and Hearing Center	Jane A. Baran, Director Audiology/Aural Rehabilitation
014	7/25/77	H.E. Douglas Engineering Sales Co.	H.E.Douglas President
015	8/12/77	Leboeuf, Lamb, Leihy & MacRae (Attorneys)	Margaret R.A. Paradis

Number	Date	Company/Address	Writer
77-5-			
016	8/11/77	Mining Enforcement and Safety Administration (MESA), U.S. Department of the Interior	Robert G. Palaso, for Donald P. Schlick, Ass't. Administrator, Technical Support
017	8/23/77	Flents Products Company, Inc.	Stuart M. Low
018	8/15/77	French Laboratory	Hugh Crozier
019	8/19/77	Industrial Safety Equipment Association	Frank E. Wilcher Executive Director
020	9/2/77	Northeastern University	David Fishken, Ph.D. Department of Psychology
021	8/18/77	Singapore Institute of Standards and Industrial Research	
022	8/26/77	Osterreichisches Normungsinstitut (Standards Institute for Government of Austria)	Rudolf Donninger
023	8/23/77	Mott Corporation	E.S. Mott
024	8/22/77	State Lobster Hatchery and Research Station (Mass.)	John T. Hughes
025	8/17/77	Marin General Hospital	Katherine M. Reilly, Audiologist
026	9/6/77	Forging Industry Association	Michael N. Winn Director of Industrial Relations and Government Affairs
027	9/20/77	Norton Company Safety Products Division	Frederick G. Crocker, Jr. Vice President and General Manager
028	9/7/77	W.H. Brady Co.	H.J. Wise
029	9/12/77	Bethlehem Steel Corporation	David M. Anderson, Ph.D. Manager, Environmental Quality Control
030	9/12/77	Civil Aeromedical Institute U.S. Federal Aviation Administration	Jerry V. Tobias, Ph.D.

Number	Date	Company/Address	Writer
77-5- 031	9/9/77	Plasmed, Inc.	John M. Ruffner President
032	9/15/77	J. I. Case Company	Lawrence H. Hodges Vice President, Technical Affairs
033	9/20/77	Aural Technology, Inc.	Thomas J. Woods President
034	9/14/77	State of North Carolina Department of Labor	L.A. Weaver Acting OSHA Director
035	9/16/77	Air Transport Association of America Operational Facility Requirements	Edwin W. Abbott Manager
036	9/14/77	Flents Products Company, Inc.	Stuart M. Low, President
037	9/13/77	The Charles Machine Works, Inc.	Gerald A. Stangl, Ph.D. Design Engineer
038	9/20/77	Industrial Safety Equipment Association	Frank E. Wilcher, Jr. Executive Director
039	9/19/77	Aural Technology, Inc.	Thomas J. Woods President
040	1/27/77	E-A-R Corporation	Charles S. Shoup General Manager
041	9/16/77	DuPont Company Energy and Environmental Division	John F. Dickey, Attorney
042	9/27/77	Taylor Products	Julian Pawline Chief Engineer
043 (Also 77-8-172)	9/25/77	City of Mountain View, California	Michael J. Percy Senior Urban Planner
044	9/7/77	Bilsom International, Inc.	Roland Westerdal President
045	9/28/77	Aural Technology, Inc.	Thomas J. Woods President
046	9/29/77	Flents Products Company, Inc.	Stuart M. Low, President

Number	Date	Company/Address	Writer
77-5-			
047	9/29/77	Australian Department of Health Psychoacoustics Section National Acoustic Laboratories	R. Waugh
048	9/26/77	Naval Ocean Systems Center	D. Lambert
049	10/21/77	Tri-Utility Hearing Conservation Program Salt River Project	Dr. G.L. Cluff Director
050	10/28/77	Aural Technology, Inc.	Thomas J. Woods President
051L	12/14/77	NIOSH, Public Health Service Center for Disease Control, DHEW	Kenneth Bridbord, M.D. Director, Office of Extramural Coordination and Special Projects
052L	12/10/77	E-A-R Corporation	Elliot H. Berger Acoustical Engineer

INDEX OF RELEVANT SUBMISSIONS FROM DOCKET 77-8: NOISE LABELING STANDARDS/GENERAL PROVISIONS

Number	Company/Address	Writer
77-5-060 (Also 77-8-904; Washington, D.C. Public Hearing)	Flents Products Company, Inc. 14 Orchard Street, P.O. Box 2109 Belden Station Norwalk, Connecticut 06852	Stuart M. Low President
77-5-061 (Also 77-8-949; San Francisco Public Hearing)	Aural Technology, Inc. 12722 Riverside Drive North Hollywood, California 91607	Thomas J. Woods President
77-5-062 (Also 77-8-954; San Francisco Public Hearing)	French Laboratory 1938 Marconi Avenue Sacramento, California 95815	Mr. and Mrs. Hugh Cozier
77-5-063 (Also 77-8-047)	290 South Ashland Avenue Lexington, Kentucky 40502	Mary O'Neal Braida
77-5-064 (Also 77-8-051)	155 Honness Lane Ithaca, New York 14850	Morris Tenenbaum
77-5-065 (Also 77-8-052)	6 Centre Place Boston, Massachusetts 02119	John Connolly
77-5-066 (Also 77-8-058)	(not available)	James Bogar
77-5-067 (Also 77-8-069)	310 West Liberty Street Rome, New York 13440	Mrs. Vernon Wall
77-5-068 (Also 77-8-414)	Kentucky Department of Labor Occupational Safety and Health Frankfort, Kentucky 40601	Larry W. Potter
77-5-069 (Also 77-8-444)	Plasticast Laboratories, Inc. 711 Penn Avenue Pittsburgh, Pennsylvania 15222	K.O. Tooker, President

INDEX OF ORAL COMMENTS DELIVERED AT 13 DECEMBER 1977 PUBLIC MEETING

Number	Company/Organization	Speaker
77-5-		
101	Flents Products Company, Inc.	Stuart M. Low President
102	Mine Safety Appliances Co.	Frank L. Lotlo
103	Wilson Products Division of ESB	Ronald J. Cox
104	E-A-R Corporation	Elliot Berger
105	NIOSH	Roy Fleming
106	Plasmed, Inc.	John M. Ruffner President
107	Norton Company, Safety Products Division	Earl W. Broker
108	Norton Company, Safety Products Division	William Newcomb
109	Industrial Safety Equipment Association	Frank E. Wilcher, Jr.
110	Reynolds Metals Company	James T. McCallum, Jr.

PUBLIC MEETING ATTENDEES
(December 13, 1977)

Angela Bannon
3M Company
1101 15th Street
Washington, D.C.
331-5581

Elliot Berger
EAR Corporation
7911 Zionsville Road
Indianapolis, Indiana 46224
(317) 293-1111

Earl W. Broker
Norton Company
2000 Plainfield Pike
Cranston, Rhode Island 02920
(401) 943-4400

Ronald J. Cox
Product Manager
Wilson Products Division of ESB
P.O. Box 622
Reading, Pennsylvania 19603
(215) 276-6161

G.C. Croushore
Mine Safety Appliances Company
600 Penn Center Boulevard
Pittsburgh, Pennsylvania 15235
(412) 273-5149

Roy Fleming
NIOSH
(617) 357-9500, x 3051

Richard P. Flynn
Marketing Manager
American Optical Company
14 Mechanics Street
Southbridge, Massachusetts
(617) 765-9711, x 2822

Bruce D. Johnson
Lab Manager
American Optical Corporation
100 Canal Street
Putnam, Connecticut
(203) 928-6554

Frank J. Lotlo
Mine Safety Appliances
201 North Braddock Avenue
Pittsburgh, Pennsylvania 15205
(412) 273-5540

Stuart M. Low, President
Flents Products, Inc.
14 Orchard Street
Norwalk, Connecticut 06850
(203) 866-2581

James T. McCallum, Jr.
Reynolds Metals Company
6603 West Broad
Richmond, Virginia 23261

William Newcomb
Norton Company
Safety Products Division
2000 Plainfield Pike
Cranston, Rhode Island 02920
(401) 943-7735

Margaret Paradis
LeBoeuf, Lamb, Leihy, and MacRae
(Counsel for Bilsom International,
Inc.)
1757 N Street, N.W.
Washington, D.C. 20036
457-7500

John M. Ruffner, President
Plasmed, Inc.
145 North Plains Road
Wallingford, Connecticut 06492
(203) 265-6761

Robert L. Strain
1231 25th Street, N.W.
Washington, D.C. 20037

F.C. White
Glendale Optical Company
130 Crossways Park Drive
Woodburg, New York
(516) 261-5800

Frank E. Wilcher, Jr.
Industrial Safety Equipment Association
1901 North Moore Street
Arlington, Virginia 22209
(703) 525-1695

APPENDIX C

ABBREVIATED LIST OF PARTIES CONTACTED THROUGH PUBLLIC PARTICIPATION PROGRAM

This Appendix contains an abbreviated list of all the organizations, associations, and individuals, both domestic and international, that the Agency was able to identify as potentially affected by, proponents of, users of, or in any way affected by the Noise Labeling Requirements for Hearing Protectors.

The Agency has actively contacted the parties on this list by direct mailings of information to them about the Hearing Protector regulation.

PUBLIC PARTICIPATION THROUGH DIRECT MAILING HEARING PROTECTORS

CATEGORY	NUMBER OF ENTRIES	EXAMPLES
Acoustical Associations	4	Acoustical Society of America National Council of Acoustical Consultants
Aerospace Association	22	American Astronautical Society American Institute of Aeronautic and Astronautics
Association of Airlines/Airports	2	Air Transport Association of America Aviation Development Council
Audiological Associations	26	American Academy of Ophathalmology and Otolaryngology Council on Education of the Deaf
Business Associations	122	American Chamber of Commerce Jaycees International
Citizens Associations	7	Citizen Action Group Call for Action
Construction Industry Associations	17	American Building Contractors Association Associated General Contractors of America, Inc.
Consumer Associations	19	Center for Consumer Affairs Consumers' Union of United States
Environmental Associations	126	John Muir Institute for Environmental Studies National Environmental Development Association
Health/Medical Associations	29	American Medical Association American Public Health Association
Hospital Associations	11	Catholic Hospital Association Surgeon General (Military Hospitals) Association of Private Hospitals
Associations of Importers/Exporters	19	World Trade Centers Association National Federation of Export Management Companies

CATEGORY	NUMBER OF ENTRIES	EXAMPLES
Industry Associations	73	Western Forest Industries Air Conditioning and Refrigeration Institute Association of Steel Distributors
Insurance Associations	11	Health Insurance Association of America International Claim Association
Legal Associations	3	American Bar Association Special Committee on Environmental Law
Retailer's Associations	4	National Retail Merchants Association
Shipbuilding Associations	9	Boating Industry Associations Boat Manufacturers Association
Sports Associations	15	National Rifle Association
Standards Organizations Associations	6	American National Standards Institute
Trade Associations	32	National Beauty and Barber Manufacturers Association Northwestern Lumbermen, Inc.
Associations of Vocational Schools	13	American Council on Industrial Arts Teacher Education American Vocational Association
Wholesalers Associations	3	Farm Equipment Wholesalers Association
Acoustical Consultants/Testing Labs	300	Acoustical Consultants, Inc. Institut de Recherche Des Tran
Congress	535	Senate and House of Representatives
Congressional Committees	11	Senate Committee on Energy and Natural Resources
Environmental Research Centers	48	Environmental Sciences Institute

CATEGORY	NUMBER OF ENTRIES	EXAMPLES
Federal Agencies	43	General Services Administration Occupational Safety and Health Administration Department of Defense
International Organizations	2	Organization for Economic Cooperation and Development
Law Firms with Environmental Interests	332	Abutano and Chisholm
Manufacturers of Hearing Protectors	70	Flents Products Excel-Silenta, Inc.
Manufacturers of Noise Pollution Control Products	134	Acoustics Manufacturing Corp. Acoustiflex Corp.
Major Manufacturers and Distributors	554	National Gypsum Corp. Eastman Kodak Co. General Electric Co.
Media: Environmental Publications	92	Journal of The Acoustical Society of America Archives of Environmental Health Cry Californian
Media: General	70	U.S. News & World Report Better Homes & Gardens
Media: Industry Specific	14	Heavy Trucking
Public Interest Groups	133	National Council of Senior Citizens American Association of Retired Persons
State and Local: Attorneys General	50	
State and Local: Departments of Transportation	50	
State and Local: Governors	50	
State and Local Users of Hearing Protectors (e.g. State Procurement Offices)	50	Purchasing Bureau, State of Maryland Material Management Bureau, District of Columbia Division
State and Local Law Enforcement	1	National Sheriffs Association

CATEGORY	NUMBER OF ENTRIES	EXAMPLES
State and Local: Mayors, Local Noise Officials and Health Department	893	L.A. Banda, City of Fremont, California Planning Department Zoning Administrator, Tuscon, Arizona Mrs. Jane Byrne, Chicago Hawaii State Department of Health
Unions	167	United Steelworkers of America United Farm Workers of America
Universities	515	Texas A&M
Manufacturers/Industries: Users of Hearing Protectors	160	Dupont The Boeing Company
Docket Entries--Hearing Protectors	48	

APPENDIX D

MANUFACTURERS AND DISTRIBUTORS OF HEARING PROTECTORS

Adcotone-Adcomold
1558 California St.
Denver, CO 80202

American Optical Safety Products
14 Mechanic St.
Southbridge, MA 01550

Bausch & Lomb
1400 N. Goodman St.
P.O. Box 450
Rochester, NY 14602

Belmar Safety Equipment, Inc.
Trenton Avenue
Barrington, NJ

Bilsom International, Inc.
1930 Isaac Newton Square, East
Reston, VA 22090

Binky Baby Products Co., Inc.
519 Patterson Avenue
Wallington, NJ

Doug Biron Associates
P.O. Box 413
Buford, GA

Blackhawk Gasket, Corp.
218 Mill St.
Rockford, IL

Bowman Distribution
Barnes Group, Inc.
852-T E. 72 St.
Cleveland, OH

E. D. Bullard, Co.
2682 Bridgeway
Sausalito, CA

CSE Corporation
600-T Seco Road
Monroeville, PA

Clark Caster, Co.
7312 W. Roosevelt Road
Forest Park, IL

H. E. Douglass Engineering
Sales Company
2700 West Burbank Blvd.
P.O. Box 7209
Burbank, CA 91505

Dunn Products, Inc.
33 S. Sangamon St.
Chicago, IL

E. I. duPont de Nemours
& Co.
Applied Technology Div.
Wilmington, DE 19898

E-A-R Corporation
376 University Avenue
Westwood, MA 02090

Eagle Druggists Supply, Co.
P.O. Box 3307
Wallington, NJ

Eastco Industrial Safety
Corporation
26-15A 123rd St.
Flushing, NY

Eastern Safety Equipment
Co., Inc.
45-17 Pearson St.
Long Island City, NY 11101

Environmental Acoustical
Research, Inc.
Insta-Mold Western Headquarters
P.O. Box 2146
Boulder, CO 80302

Erb Plastics, Inc.
P.O. Box 156
Woodstock, GA 30188

Feeder Corporation of
America
4429-T James Place
Melrose Park, IL

Cesco Safety Products
100 East 16th St.
Kansas City, MO 64108

David Clark Co., Inc.
360 Franklin St.
P.O. Box 155
Worcester, MA 01613

Curtis Safety Products Co.
P.O. Box 61
Webster Square Station
Worcester, MA 01608

Foam Products, Inc.
York Haven, PA

French Laboratory
1938 Marconi Avenue
Sacramento, CA 95815

General Scientific Equipment Company
N. Limekiln Pike and Williams Avenue
Philadelphia, PA

Hal-Hen Company
36-14A 11th St.
Long Island City, NY

Hechler Brothers, Inc.
22-19 37th Avenue
Long Island City, NY 11101

Industrial Noise Control, Inc.
785-T Industrial Dr.
Elmhurst, IL

3M Company
Occupational Health and Safety Products Department
3M Center
St. Paul, MN 55101

Martindale Electric, Co.
1365 Hird Avenue
Cleveland, OH

The Fibre-Metal Products Company
Baltimore Pike at Brinton Lake Road
Concordville, PA 19331

Firesafe, Inc.
1202 Monroeville Avenue
Turtle Creek, PA

Flents Products Co., Inc.
14 Orchard St.
P.O. Box 2109
Belden Station
Norwalk, CN 06850

Dr. Frank Corporation
P.O. Box 232
Cape Coral, FL

Frontier Industrial
3521 Sunset Blvd.
Los Angeles, CA 90026

Glendale Optical Co., Inc.
130 Crossways Park Dr.
Woodbury, NY 11797

Hearing Conservation Ltd.
Amplivox House
Beresford Avenue
Wembley, Middlesex
England HAO IRU

Hocks Laboratories
935 N.E. Couch St.
Portland, OR 97214

Industrial Products, Co.
21 Cabot Road
Langhorne, PA

Marion Health and Safety, Inc.
9233 Ward Parkway
Kansas City, MO 64114

Mediprint, Inc.
2510 Sutton Blvd.
St. Louis, MO 63143

Mine Safety Appliances, Co.
400 Penn Center Blvd.
Pittsburgh, PA 15235

New Jersey Safety Equipment, Co.
1680 Stuyvesant Avenue
Union, NJ

Ocean Pool Supply Co., Inc.
17 Stepar Place
Huntington Station, NY

Perfection Supply, Co.
6434 N. Central Avenue
Chicago, IL

Pure Rubber Products, Co.
3 Ray Place
Fairfield, NJ

Safety Clothing and Equipment, Co.
4900 Campbell Road
Willoughby, OH

Safety Ear Protector, Co.
5356 West Pico Blvd.
Los Angeles, CA 90019

Sellstrom Manufacturing, Co.
Palatine, IL 60067

Sigma Engineering
Norton Safety Products Division
11320 Burbank Blvd.
North Hollywood, CA 91601

Sound Master Corporation
1530 Broadway
Oakland, CA 94612

Surgical Mechanical Research, Inc.
900 W. 16th St.
P.O. Box 1185
Newport Beach, CA 92663

Material Flow, Inc.
835 N. Wood St.
Chicago, IL 60622

Morse Safety Products, Co.
18103 Roseland Avenue
Cleveland, OH 44112

Norton Company
Safety Products Division
2000 Plainfield Pike
Cranston, RI

Ohio Valley Safety Co., Inc.
523 N. Commerical Dr.
Steubenville, OH

Pulmosan Safety Equipment,
Corporation
30-48 Linden Place
Flushing, NY

Rye Industries, Inc.
125 Spencer Place
Mamaroneck, NY

Safety Direct
P.O. Box 8907
Reno, NV 89507

Scintrex Audio Division
Scintrex, Inc.
400 Creekside Drive
Amherst Industrial Park
Tonawanda, NY 14150

Russ Simpson, Co.
21908 Schoenherr Road
Warren, MI

Southern First Aid Supply, Co.
1120 Piedmont Drive
Lexington, NC 27292

Talon Industries, Inc.
55-T Knickerbocker Avenue
Bohemia, NY

Titan Abrasive Systems, Inc.
P.O. Box 3-T
Furlong, PA

Wade Products, Co.
12 Arlington Drive
Croton, NY

George W. Warner & Co., Inc.
252-A Lafayette St.
New York, NY

Willson Products Division
ESB Incorporated
2nd and Washington Streets
P.O. Box 622
Reading, PA 19603

Tasco Corporation
22 Alemida Avenue
East Providence, RI

United States Safety
Service Company
1535 Walnut St.
Kansas City, MO 64108

Welsh
A Textron Company
2000 Plainfield Pike
Cranston, RI